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ASIAN BIOTECHNOLOGY AND DEVELOPMENT REVIEW

Vol. 6 No. 2 March 2004

- Collaborative Research in Biotechnology and Role of Government-sponsored Research Institutes (GRIs)
  Yong-Gil Lee and Yun-Chul Chung
- Biodiversity and the Millennium Development Goals
  Balakrishna Pisupati and Emilie Warner
- Agricultural Biotechnology Sector in India: Issues Impacting Innovations
  A. Damodaran
- Global Status of Commercialized Transgenic Crops: 2003

  Seventh Conference of Parties to the CBD

  Biotechnology Enterprise in Germany

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ISSN: 0972-7566

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This journal is abstracted in ***Cab International*** and ***Science of Science,*** of Council for Scientific and Industrial Research (CSIR), New Delhi.

ASIAN
BIOTECHNOLOGY AND DEVELOPMENT
REVIEW

Cuk- H03799-2-P023739

P23739

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Contents

Collaborative Research in Biotechnology and Role of Government-sponsored Research Institutes (GRIs) 1
Yong-Gil Lee and Yun-Chul Chung

Biodiversity and the Millennium Development Goals 15
Balakrishna Pisupati and Emilie Warner

Agricultural Biotechnology Sector in India: Issues Impacting Innovations 41
A. Damodaran

Global Status of Commercialized Transgenic Crops: 2003 53

Bio News 61

Document 71

Bio Web 97

Bio Stats 101

Collaborative Research in Biotechnology and Role of Government-sponsored Research Institutes (GRIs)

Yong-Gil Lee[*]
Yun-Chul Chung[**]

Introduction

Government-sponsored research institutes (GRIs) play an important role and occupy a strategic position in national innovation system. Especially, GRIs lead various kinds of research in cutting-edge research fields or technology in areas such as nano-technology and biotechnology, in which private firms cannot invest so much because of high cost and risks. The Korean government designed National Technology Roadmap (NTRM) to develop those technologies efficiently and stimulate collaborative research among universities, firms and public research institutes. NTRM contains of key technology list to be developed and promotion plans year by year to 2012. In this paper, we analyse the technology list of NTRM, especially the list in biotechnology field and matched the GRIs' research areas to the technology list. Through this matching and analysis, we suggest a few ideas about how to collaborate effectively among GRIs.

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There could be mainly two types of collaboration patterns among GRIs. The one is vertical collaborative relationship, and the other is horizontal. Vertical collaborative relationship is formed when a technology cluster grouped by technological similarity has vertical structure. Horizontal collaborative relationship is formed when a cluster has horizontal structure. In these two cases, the role of 'technological coordinator', which mainly conducts the role of funding agency, R&D planning, and designing the collaborative research, etc, is important.

Reasons for collaborative research

Knowledge production methods are changing from Mode 1 to Mode 2.[1] While Mode 1 production process has 'hierarchical', 'disciplinary', 'determinate' characteristics, Mode 2 process has 'networked', 'trans-disciplinary', 'reflexive' features. In biotechnology field, the equivalent changes are also happening. From chance discovery and random screening to rational drug design, screening by design, drug designing methods are changing.[2] The revolution in molecular biology could make this change happen. Dramatic advances in genetics, genetic engineering, peptide chemistry and molecular/cell biology have changed a lot of questions. In his study (Henderson, 1994),[3] in hypertensive drugs, the question is changed from "find me something that lower blood pressure in rats" to "find me something that inhibits the action of the angiotensin-2 converting enzyme.

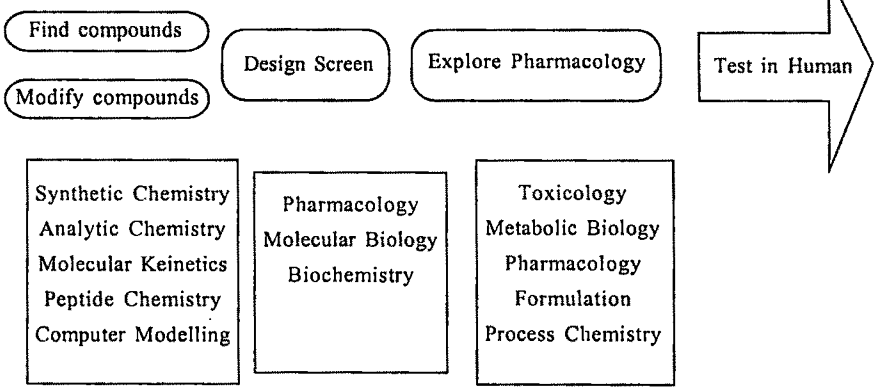
In the age of chance discovery and random screening, there is a 'target rich' environment but little knowledge of biological underpinnings of specific diseases is available. Some firms and institutes have conducted large scale screening of thousands of compounds. As a result, there are enormous libraries of chemical compounds. In the era, there was relatively little communication of knowledge. But, in the age of rational drug design and screening by design, we could understand the mechanism of action of some existing drugs and the biochemical and molecular roots of many diseases. In this era, high level of information flow across the boundaries of scientific disciplines and therapeutic areas by using cross-disciplinary teams was possible.

What are the factors and causes of this change? A lot of causes could be explained. Among them, publicly funded research, 'academic' companies, and the characteristics of biotechnology itself are important factors. Lots of papers and patents addressing knowledge about the cause of disease were produced in universities and institutes. As a result, substantial advances in physiology, pharmacology, enzymology, and cell biology led to enormous progress. Universities and public research institutes played major roles. On the other hand, a lot of 'academic' pharmaceutical companies, especially dedicated biotechnology firms (DBFs) encourage both publication and the presentation of results outside the firms. Those firms also funded academic research. The characteristics of biotechnology are important, too. The industry of biotechnology is still a young science-based industry, but a burgeoning field. Rival's research efforts are complements rather than substitutes. Knowledge of their false starts and failures may help to shape one's own research programme. But in the triple helix (universities, government GRIs and industry) concept, modern bioscience has caused a massive shift in research firepower away from the 'industry' part of the helix to the 'university' and 'GRIs' component by virtue of massive rise in public research investment from the 'government' part.[4]

Collaborative research in biotechnology

Multidisciplinary knowledge fundamental to leading-edge drug discovery and the complex reality of rapidly developing fields is required. To develop a good drug, the following disciplinary fields described in Figure1 are needed.

Figure 1: Multidisciplinary approach to a new drug development



Research breakthroughs demand a range of intellectual and scientific skills that far exceed the capabilities of any single organization. There were as many as 34 coauthors in Alzheimer's disease in 'Nature'.[5] The development of an animal model for Alzheimer's disease appeared in a report coauthored by 34 scientists affiliated with two new biotech companies, one established pharmaceutical firm, and a few leading research universities.[6] There were as many as 45 coauthors in breast and ovarian cancer in 'Science' (Henderson, 1994). A publication identifying a strong candidate for the gene determining susceptibility to breast and ovarian cancer featured 45 coauthors drawn from a biotech firm, U.S. medical schools, government research laboratories, one established pharmaceutical company, etc.[7]

It is generally known that the propensity to cooperate on R&D is higher for firms and institutes from science-based or high technology based sectors with relatively high R&D intensity. Absorption capabilities depend on specific investment, including the existence of an R&D department and enough qualified human resources. Internal R&D capabilities have complex influences on the propensity to cooperate. On the one hand, cooperation may become necessary because internal resources are insufficient to meet the firms' and institutes' strategic goals. On the other hand, the existence of adequate absorption capabilities increases the returns firms and institutes can expect from access to external resources. Especially, this second effect has been found to be stronger in biotechnology (Arora and Gambardella, 1990).

There could be two types of collaborative research patterns among research organizations. Vertical collaborative relationship is formed when the technology cluster grouped by similarity has vertical structure as shown in Figure 2. The technological coordinator plays a role of tuning the flow of the research among each stage. So, the technological coordinator should cover the whole process of research and development. Generally, vertical R&D cooperation is more frequent than horizontal cooperation with rivals.

Horizontal collaborative relationship is formed when the technology cluster has horizontal structure as shown in Figure 3. The technological coordinator should cover main sub areas of the cluster. Horizontal cooperation with rivals is more frequent in high-tech sectors.

Figure 2: Vertical technology cluster and technology coordinator

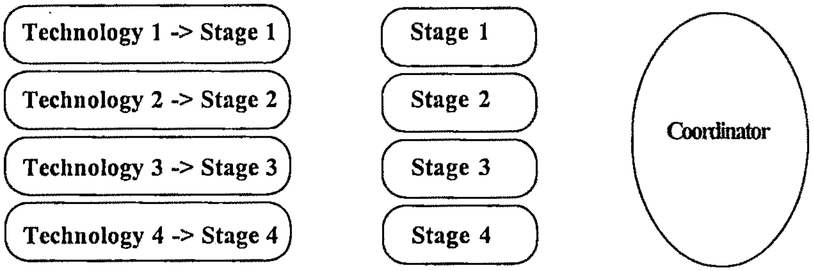
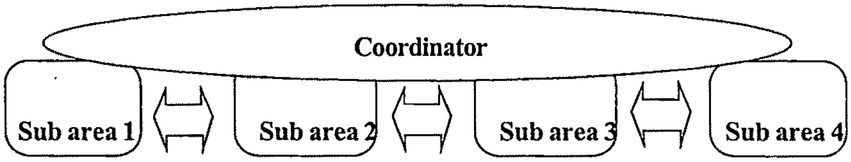


Figure 3: Horizontal technology cluster and technology coordinator



The roles of technological coordinators include:

- R&D planning in the technology cluster
- Funding agency
- Conducting related R&D programmes
- Designing the collaborative research among 'Triple Helix'
- Commercializing technology, especially transferring technology to private sectors.

Through the behaviour of technology coordinator, we can minimize transaction cost and maximize the synergy of collaborative research.

Collaborative research among GRIs

National technology roadmap (NTRM)

Korean government planned to distribute limited R&D resources efficiently through the "selection and concentration" strategy to enhance national competitiveness. It means that intensively supporting technologies, which are likely to acquire world-level superiority in competitiveness, is important.

For this purpose, the government, mainly Ministry of Science and Technology, analyzed industries and technological trends internally and externally, selected promising key technologies that can acquire global competitiveness based on 10 years time span, and designed national technology road map (NTRM) for promoting strategic research and development programmes.[8]

Beyond forecasting industrial development and analyzing technological trend, NTRM proposes visions 10 years from now to enhance the national competitiveness, defines strategic technologies, and suggests a national technology roadmap for key technologies. NTRM provides guidelines for sharing strategies related to key technologies among the government and private sectors and for conducting research and development.

The technology list of Life Science in NTRM is identified in Table 1. Some 21 technologies are listed and analyzed. These technologies are mainly composed of such fields as 'new drug discovery and development', 'innovation in diagnosis and disease treatment', and technologies related to 'Rehabilitation'. From now on we analyze the research areas of five GRIs associated with biotechnology. There are KRIBB (Korea Research Institute of Bioscience and Biotechnology), KIST (Korea Institute of Science and Technology), KRICT (Korea Research Institute of Chemical Technology), KFRI (Korea Food Research Institute), and KIOM (Korea Institute of Oriental Medicine).

Vertical and horizontal technology clusters

The technology cluster related to 'new drug discovery and development' in NTRM is structured vertically. The number of technologies related to 'new drug discovery and development' in NTRM is nine. We can construct the technology cluster of 'new drug discovery and development' as one vertical process. To discover new drugs effectively, target recognition should be conducted at first. Target recognition category contains the target recognition technology, and the target validity verification technology. Then, candidate substance should be screened. The main technologies associated with this category are candidate substance screening technology, candidate substance

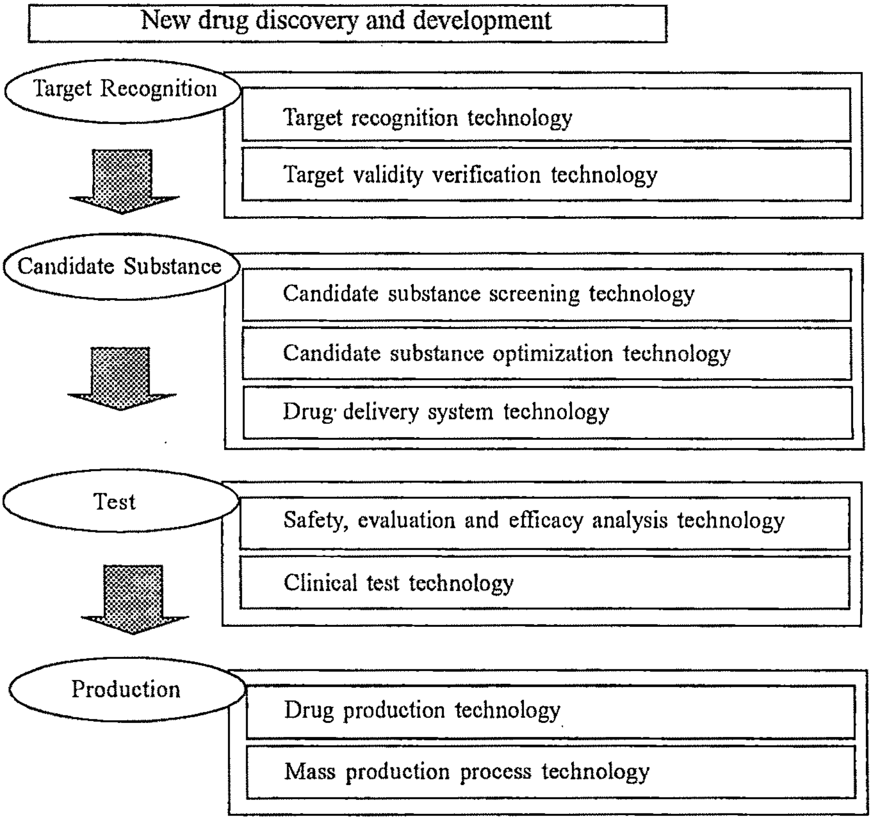
Table 1: The 21 key technologies in life science in national technology roadmap

	Technology title
A	Biological diagnosis technology
B	High-speed analysis system technology
C	Target recognition technology
D	Target validity verification technology
E	Candidate substance screening technology
F	Candidate substance optimization technology
G	Mass production process technology
H	Drug production technology
I	Drug delivery system technology
J	Safety, evaluation and efficacy analysis technology for medicine
K	Clinical test technology
L	Handling technology of biological signal process
M	Handling technology of biological image process
N	Body function analysis technology
O	Bio-machine/robotics technology
P	Bio materials technology
Q	Stem cell cultivation technology
R	Gene identifying and conveying technology
S	Monitoring technology of biological function
T	Bio-information creation and preservation technology
U	Bio-information utilization technology

optimization technology, and drug delivery system technology. Next test should be done, and then production begins. The four processes are linked vertically. We can represent the process in Figure 4.

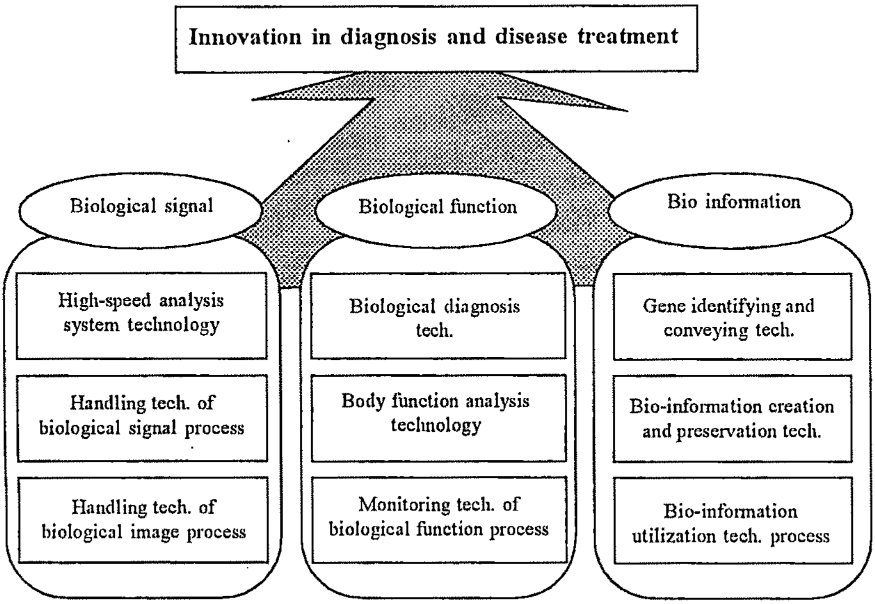
Horizontal collaborative relationship is formed when the cluster has horizontal structure. The technology cluster related to 'innovation in diagnosis and disease treatment' is structured horizontally. In this case, GRIs should form horizontal relationship. Technologies related to 'innovation in diagnosis and disease treatment' in NTRM are as follows.

Figure 4: Vertical technology cluster: new drug discovery and development


New drug discovery and development
Target Recognition
Target recognition technology
Target validity verification technology
Candidate Substance
Candidate substance screening technology
Candidate substance optimization technology
Drug delivery system technology
Test
Safety, evaluation and efficacy analysis technology
Clinical test technology
Production
Drug production technology
Mass production process technology

The technologies related to 'innovation in diagnosis and disease treatment' could be structured horizontally as in Figure 5. It could be divided into three major categories. Each category forms the horizontal relationship. The category associated with 'Biological Signal' contains the high-speed analysis system technology, handling technologies of biological signal process, and handling technology of biological image. The category related to 'Biological Function' has such technologies as biological diagnosis technology, body function analysis technology, and monitoring technology of biological function. The bio-information category consists of gene identifying and conveying technology, bio-information creation and preservation technology, and bio-information utilization technology. Each category is structured relatively

Figure 5: Horizontal technology cluster: innovation in diagnosis and disease treatment


Innovation in diagnosis and disease treatment
Biological signal
High-speed analysis system technology
Handling tech. of biological signal process
Handling tech. of biological image process
Biological function
Biological diagnosis tech.
Body function analysis technology
Monitoring tech. of biological function process
Bio information
Gene identifying and conveying tech.
Bio-information creation and preservation tech.
Bio-information utilization tech. process

horizontally compared with the technology cluster of 'new drug discovery and development'. Here, the own success in each technology field is more important. Then the horizontal collaborative relationship could be formed effectively.

The technology list related to 'Rehabilitation' contains bio-machine/robotics technology, bio-materials technology, and stem cell cultivation technology.

Technological coordinators in the collaborative research

In these two cases, the role of 'technological coordinator' is important. Technological coordinator plays a role like tuning the flow of the research between each research stage in vertical collaborative research. Technological coordinator also plays a role like combining each research output in horizontal collaborative research. It also plays the role of R&D planning in the technology cluster, funding agency, conducting related R&D programmes, designing the collaborative research among 'Triple Helix', commercializing technology, especially transferring technology to private sectors.

How can we select the technological coordinators in the research process? Figures 6 and 7 show the prominent candidates of technological coordinators in terms of research area covered by GRIs. According to Figure 6, KIST and KRIBB cover the whole vertical processes of 'new drug discovery and development'. Other GRIs cover the field partly. To succeed in developing the new drugs, the four procedures should be conducted very efficiently and should be closely linked together. The vertical relationship between GRIs is accented and the R&D programme should be conducted collaboratively. From Figure 7, we can choose KRIBB as a good coordinator in the horizontal technological cluster, 'innovation in diagnosis and disease treatment'.

Figure 6: Technological coordinators in vertical technology cluster

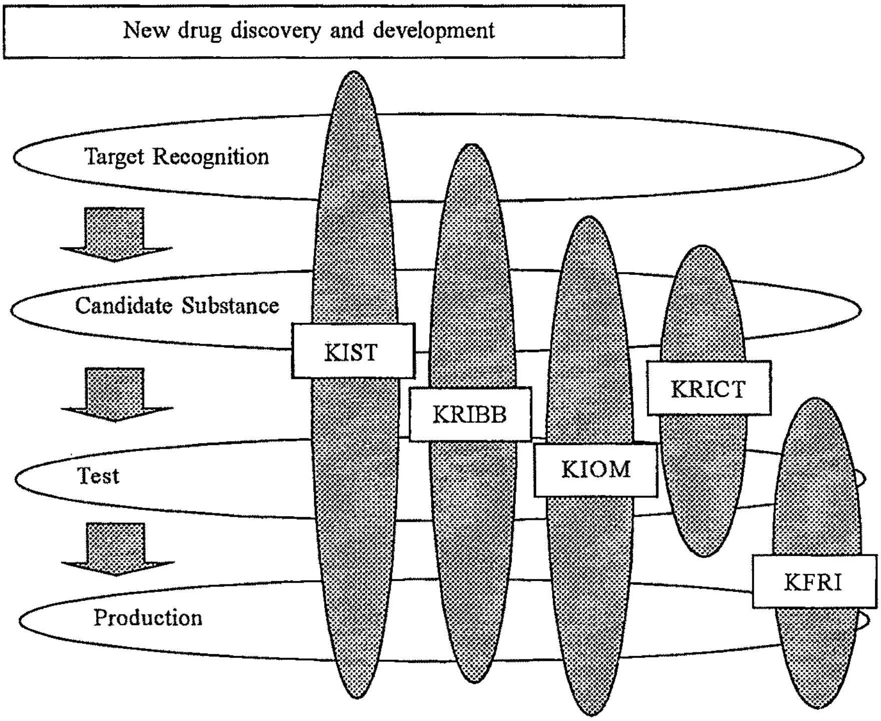
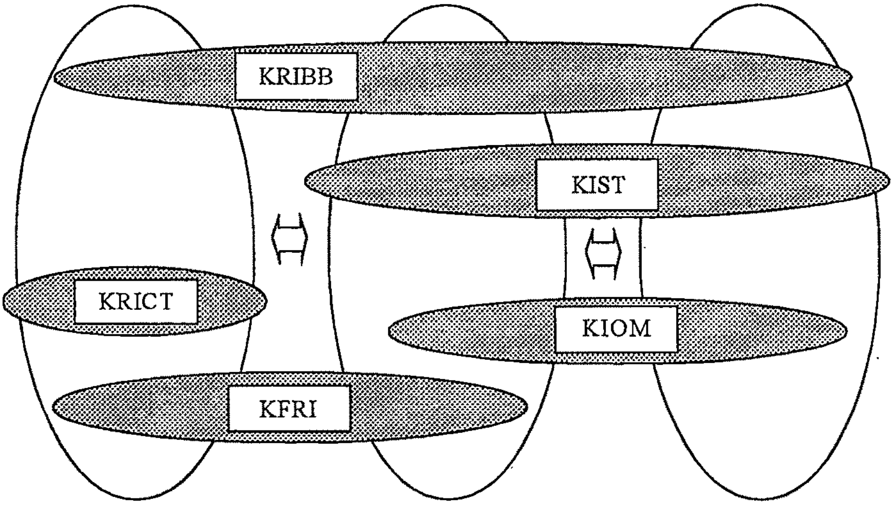


Figure 7: Technological coordinators in horizontal technology cluster



Conclusion

It is clear that there are two types of collaborative research patterns among GRIs. Vertical collaborative relationship is formed when the technology cluster grouped by similarity has vertical structure. For example, the technology cluster related to 'new drug discovery and development' is structured vertically. When GRIs should conduct co-research, they should consider this point. We could construct the technology cluster of 'new drug discovery and development' as one vertical process, target recognition, candidate substance, test, and then production. The four processes are linked vertically. Among GRIs, KIST and KRIBB cover the whole vertical process of 'new drug discovery and development'. Other GRIs cover the field partly.

On the other hand, horizontal collaborative relationship is formed when the cluster has horizontal structure. The technology cluster related to 'innovation in diagnosis and disease treatment' is structured horizontally. It could be divided into three major categories. Each category forms the horizontal relationship. The categories are biological signal, biological function, and bio-information. In this case, GRIs should form horizontal relationship.

In these two cases, the role of 'technological coordinator' is important. Technological coordinator plays a role like tuning the flow of the research between each research stage in vertical collaborative research. So if KIST and KRIBB could be technological coordinator, the whole process may probably be linked effectively. Technological coordinator also plays a role like combining each research output in horizontal collaborative research. Those two institutes can play the role of coordinator well in the horizontal cluster in view of tuning the research flow.

Endnotes

[1] Etkowitz & Leydesdorff, 1997.

[2] Henderson et al., 1999.

[3] Henderson, 1994.

[4] Cooke, 2002 and 2003.

[5] Henderson, 1994.

[6] Nature, Feb., 1995.

[7] Science, Oct., 1994.

[8] Ministry of Science and Technology *et al.*, 2002.

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Biodiversity and the Millennium Development Goals

Balakrishna Pisupati[*]
Emilie Warner[**]

Introduction

The variety of life forms on earth, including genes, species and ecosystems, is known as biological diversity or biodiversity. Loss of biodiversity results in serious reductions in the goods (such as food, medicine and raw materials) and services (such as clean water and nutrient cycling) provided by the earth's ecosystems, which make human survival and economic prosperity possible (Anonymous 2002).

The Millennium Development Goals (MDGs) were formally established when the United Nations General Assembly adopted the Millennium Declaration in September 2000. Adoption of the Millennium Declaration paves a significant way to addressing issues of poverty eradication and sustainable development. Through a set of targets and dates, the MDGs provide a framework for measuring development progress. They also reinforce the commitment of the international community for a comprehensive and integrated approach to sustainable development.

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Biodiversity plays an important role in ensuring that the targets of the MDGs for sustainable development are successfully achieved. However, the links between biodiversity and the path to achieving the MDGs have not been made explicit. The first section of this paper provides an introduction to the benefits of biodiversity and the Millennium Development Goals. The importance of biodiversity to development objectives is also discussed in the context of the WEHAB Initiative and the Convention on Biological Diversity. The second section of this paper provides a more detailed discussion of the role of biodiversity in achieving the targets of each of the MDGs. The third section considers links between climate change, biodiversity and the MDGs. Finally, section four provides the conclusions and recommendations for ways forward and future activities.

Biodiversity

Through the provision of biological resources and ecosystem services, biodiversity is an essential component of human development and human security. Through agriculture, forestry and fishing, biodiversity provides crops, timber and fish and contributes significantly to national economies and employment. Ecosystem goods range from food and water to timber and fodder to genetic resources. In addition, ecosystem provide essential services including nutrient cycling, air and water purification, flood and drought mitigation and soil production, free of charge. These services cannot be replaced at a reasonable price (WRI, 2002).

The direct economic benefits of biodiversity run into trillions of dollars per year (Costanza *et.al.* 1997). Some of the significant benefits include: an annual market value of crop production in the United States to tunes of about US$40 billion which is completely dependent on insect pollinators; biological pest control that saves an annual revenue of US$ 100-200 billion; and, biological nitrogen fixation has an estimated annual worth of US$50 billion. While recognition of the values of the goods and services that biodiversity offers – both direct and indirect – is increasing, the relationship between the role of biodiversity in environmental sustainability, poverty reduction and sustainable development needs further attention and understanding.

The millennium development goals

The Millennium Development Goals (MDGs) were formally established when the United Nations General Assembly adopted the Millennium Declaration in 2002. They address issues of poverty eradication and sustainable development through a set of targets and dates. Achieving these targets is the responsibility of national governments.

One of the significant features of the MDGs is that they seem to focus on developmental issues, leaving options of how to implement actions to achieve the goals open for interpretation. Goal 7 of the MDGs focuses on ensuring environmental sustainability without any explicit mention of the role of biodiversity and natural resources. However, the role of biodiversity in ensuring that the targets of the MDGs are successfully achieved is well recognised. Attempts are being made to mainstream biodiversity into not only MDG 7, but also across other MDGs, as achieving the targets of the MDGs will directly or indirectly impinge on the status and use of biodiversity.

Convention on biological diversity

One of the landmark outcomes of the 1992 Earth Summit was the adoption of the Convention on Biological Diversity (CBD), which has so far been ratified by 189 countries. The CBD focuses on conservation of biodiversity, sustainable use, and fair and equitable sharing of benefits arising out of the use of biodiversity. The CBD is one of the most important international conventions and is implemented widely and in many cases effectively.

Discussions through the CBD Conference of Parties set an international agenda to reduce the rate of loss of biodiversity by 2010. The so-called "2010 targets" are currently under discussion and indicators, measures and options are being identified. A significant element of CBD is the underpinning it provides for sustainable development through biodiversity conservation. It is thus imperative to link CBD both to MDGs and WEHAB principles. The following Table 1 provides linkages between biodiversity and livelihoods (Koziell 2001), which exemplifies the need for an integrated approach for biodiversity conservation and sustainable livelihood development.

Table 1: Livelihood and biodiversity change scenarios

	Livelihood Improvement	Livelihood Decline
Biodiversity maintained or increased	**1.** Poor and indigenous communities (with marginal agricultural potential) will maintain and enhance biodiversity – either because they have no purchasing power to obtain commercial products and therefore no alternative support for their livelihoods, or because they choose to, for cultural or religious reasons.	**2.** Exclusionary PAs that yields conservation benefits for the international community, but at a cost to local communities whose access to resources is restricted.
Biodiversity loss	**3.** Land is converted to industrial agricultural plantations of high-yielding varieties for domestic and export markets. Efficiency gains from economies of scale can reduce product prices, benefiting the urban poor, who spend up to 80 per cent of their income on food.	**4.** Intensive and large-scale extraction of resources such as timber by distant companies can lead to losses of other biological resources, such as NTFPs, which may be critical sources of income or subsistence food for small-holder agriculturalists.

Source: Koziell 2001.

A DFID, IUCN and EC study on identifying the role of biodiversity in development identified the following seven principles as the guiding principles for biodiversity in development cooperation. The key underlying understanding is the fact that biodiversity is not just a measure of sustainable development or a concern of environmentalists, it is essential for many people's lives.

Some specific issues and operational options to link CBD targets and achieving MDGs

After the adoption of MDGs by the UN General Assembly in September 2000, various fora acknowledged the important relationship between biodiversity and the MDGs. In April 2002, the 6th Conference of Parties to the Convention on Biological Diversity, recognizing that biodiversity underpins sustainable development, established 2010 as the target year for halting biodiversity loss. In May 2002, UN Secretary General set out the five WEHAB priorities for the World Summit on Sustainable Development (WSSD). The WSSD Plan of Implementation called for actions from all sectors to significantly address reducing the rate of loss of biodiversity.

Considering the importance of addressing issues of mainstreaming biodiversity into MDGs, IUCN Regional Biodiversity Programme, Asia in collaboration with UNDP and Government of India, organized an Asia Regional Workshop on the issue in India between 6-11 April 2003. The recommendations from the workshop form the basis for this section and the recommendations are detailed as specific activities under each of the MDG as they relate to issues of biodiversity. In addition, UNDP, UNEP-WCMC and others organized an international workshop on addressing the issues of biodiversity in relation to MDGs and WEHAB (The 'Biodiversity after Johannesburg' meeting in London), outcomes of which also encourage the need to address synergies between MEAs, mainstreaming biodiversity into MDGs as options to achieving sustainable development.

Goal on poverty and role of biodiversity

Goal 1 - Eradicate extreme poverty and hunger

Targets: Halve, between 1990 and 2015, the proportion of people whose income is less than $1 a day; and halve, between 1990 and 2015, the proportion of people who suffer from hunger.

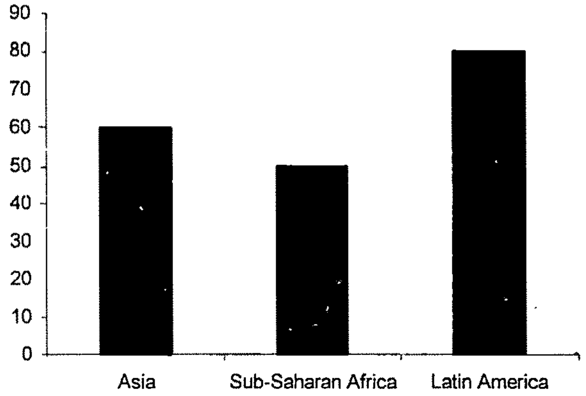
The Millennium Development Goals reflect the multifaceted nature of poverty, with each goal illustrating a different aspect of poverty. The MDGs are an attempt to operationalise the multidimensional approach to poverty, focusing on selected indicators. Since biodiversity impacts issues of poverty, a focus on using biodiversity equitably and sustainably is fundamental to strategies and actions to eradicate/reduce poverty and to achieve sustainable development.

Links between biodiversity and poverty

The poverty goal of the MDGs addresses issues of extreme poverty, hunger and malnutrition, which are closely related to the livelihoods and vulnerability of households. Rural households derive a significant proportion of their food and income from biological resources and, therefore, the availability and sustainability of biological resources is of direct relevance to poverty reduction for these people. Additionally, a large proportion of poor people live in marginal environments and in areas with low agricultural productivity or in fragile lands (see Figure 1 below).

In these environments, there is a high dependency on genetic, species and ecosystem diversity to support their livelihoods. That is, aspects of

Figure 1: Percentage of the poorest living on fragile land

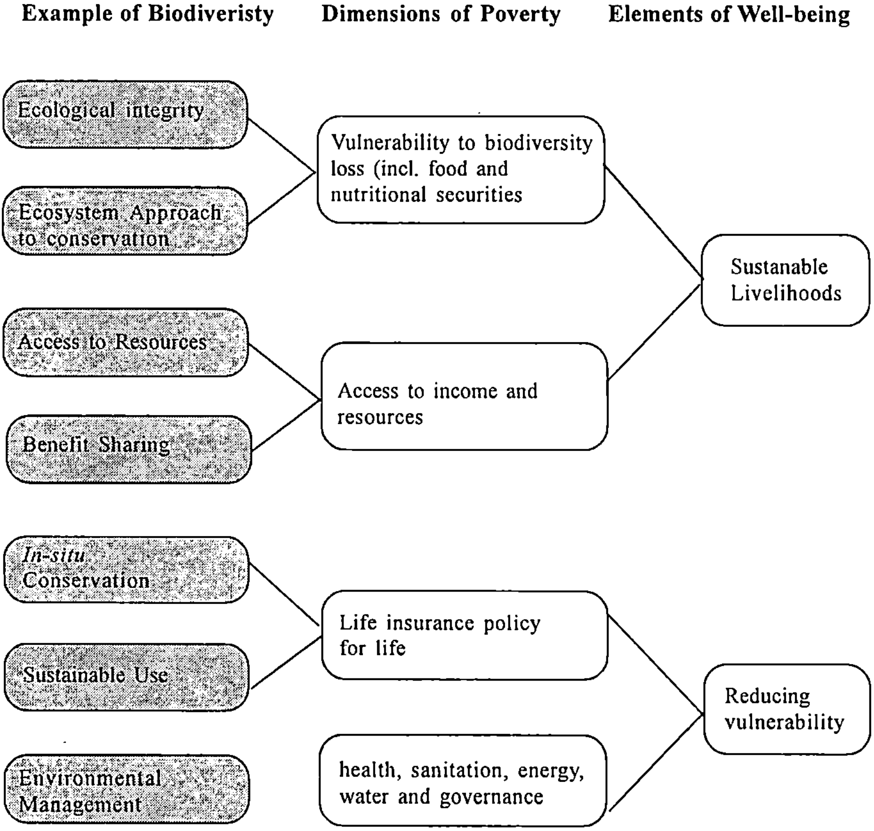


Source: World Bank 2002.

biodiversity are of direct and indirect importance to food availability, health, nutrition, house-hold development, income generation and vulnerability. Furthermore, improvements to core productive assets (including biodiversity-related factors of soils, water, trees and natural vegetation) is identified by the Millennium Project Task Force 2 on Hunger as the first step of the principle strategy for reducing undernutrition in households in such high-risk environments (Scherr 2003).

The following Figure 2 illustrates links between biodiversity and poverty and Box 3 provides a discussion of relationship between poverty and the environment.

Figure 2: Biodiversity links to the dimensions of poverty



P23739

The World Bank and IMF review of Poverty Reduction Strategy Paper (PRSP) suggested that the national PRSP can guide the implementation of MDGs even though the indicators used are different. However, none of the PRSPs developed so far address the issue and importance of biodiversity as a critical element of poverty reduction at national level nor the impacts of biodiversity in livelihood securities.

Links to CBD

Integration of MDG 1 into the 2010 targets of the CBD will also help to ensure the targets of MDG 1 are met while, at the same time, ensuring the sustainable use of biodiversity. Broadly, the following may be considered as ways to integrate issues of MDG 1 and CBD targets of 2010:

- Improving poor peoples' access to, and tenure of, biodiversity resources;
- Involving the poor in decision and policy making;
- Providing market linkages and sustainable use practices;
- Investing in research and development on how to improve rural incomes; and
- Developing mechanisms to continue or enhance public interest in biodiversity – maintaining products and services.

Outputs from Asia Regional Workshop

Some of the more specific actions and interventions to achieve MDG 1, while ensuring the sustainable use of biodiversity include:

- Improve the Human Resources Capital through revision of education policies, training and capacity building that encourages income generation.
- Achieve population control targets by raising awareness, empowerment, education and equity through development and implementation of appropriate policies – thus reducing the pressure on biodiversity.
- Develop income generation opportunities through sustainable livelihoods using Public-Private Sector partnerships with supporting policies and investments at local levels.
- Achieve minimum nutritional standards of people by: promoting cultivation of nutritional crops, drought-resistant varieties; setting up

community seed banks; provision of access to nutritional food; raising awareness on removing hidden and transient hunger.

- Promote access and benefit sharing activities (i.e., benefits of conservation efforts should be targeted to the poor (stakeholders) by: supporting activities on *ex-situ* cultivation; developing policies/ legislations on sharing of benefits including the mechanisms for enforcement; and raising awareness.
- Promote sustainable use practices and market linkages by developing policies and regulations through cooperatives and other appropriate mechanisms.
- Understand the economic values of biodiversity and empower local communities on achieving economic gains (within the legal ambit) by developing suitable market linkages and strategies.
- Raise the awareness of communities on values of biodiversity by: assessing the economic value of biodiversity; raising awareness; building capacities of communities; identifying and supporting elements of biodiversity that impact livelihoods.
- Promote sustainable agricultural practices by: providing incentives to farmers for following sustainable practices; supporting use of modern and traditional technology blends; supporting effective Public Distribution System.

Health goals and biodiversity

Goal 2 - Reduce child mortality

Target: Reduce, by two-thirds, between 1990 and 2015, the under-five mortality rate.

Goal 3 - Improve maternal health

Target: Reduce by three-quarters, between 1990 and 2015, the maternal mortality ratio.

Goal 4 - Combat HIV/AIDS, Malaria and other diseases

Targets: Have halted by 2015 and begun to reverse the spread of HIV/ AIDS; Have halted by 2015 and begun to reverse the incidence of malaria and other major diseases.

Biodiversity provides one of the significant contributions to achieving MDGs 4, 5 and 6. Recent studies led by Harvard Medical School reveal that biodiversity plays a crucial role not only in providing medicines to deal with issues of health and nutrition, but ecosystems play a significant role in dealing with diseases like malaria and others (Chivian 2002).

The commission on the nutrition challenges of the 21st century, in its report titled "Ending malnutrition by 2002: An agenda for change in the millennium" has pointed out that some 30 million infants are born each year in developing countries with intra-uterine growth retardation (IUGR). This represents about 24 per cent of all new births in these countries (Philip 2000). IUGR has been associated with maternal nutritional depletion and low birth weight children are characterised by mental impairments. The MDGs recognise these issues and aim to address issues of reducing mortality rates of both new-borns as well as the maternal mortality. The following Box 1 outlines strategies implemented under Thailand's Nutritional Security Pact and its

Box 1: Thailand's nutrition security compact

During the past 10 years, Thailand has achieved remarkable progress in reducing maternal mortality as well as the incidence of Low Birth Weight (LBW) children. The strategy consisted of the following components:

- Eliminate severe, moderate and mild protein-energy malnutrition (PEM)
- Monitor growth among all pre-school children and provide food supplements where needed
- Mainstream nutrition in health, education and agricultural policies
- Retrain and retool existing staff and mobilise community volunteers. Choose one community volunteer for every 10 households and build their capacity
- Encourage breast feeding and organise school lunch programmes
- Promote home gardening, consumption of fruits and vegetables, aquaculture and food safety standards
- Introduce an integrated food safety net with emphasis on household food and nutrition security.

The positive impact of the above Nutrition Security Compact is evident from the decline of maternal mortality from 230 per 100,000 live births in 1992 to 17 in 1996 (Philip 2000). Thailand's initiative in organising a Community Volunteer Corps for Household Nutrition Security is worth or emulation by other nations.

Source: Swaminathan M.S. 2001.

Box 2: Examples of values of natural products as pharmaceuticals

A question that is often asked is whether there is any data on the financial value of natural product-derived drugs for pharmaceutical companies. A recent analysis by Newman and Laird (1999) demonstrated that the percentage of sales (not profits) derived from natural products or related compounds ranged from 50 per cent for Merck to 8 per cent for Johnson and Johnson, with the majority of companies falling between 15 and 30 per cent. Companies were not included unless they had at least one drug that sold for more than US $1 billion. It should be emphasized that this was a one-time study using only 1997 sales figures for drugs that sold more than US $1 billion that year, and that almost all of the natural product-derived drugs in this analysis were microbial in origin. It was not for another two years that the first plant-derived drug to break sales figures of US $1 billion arrived, and that was Taxol.

Source: Chivian. E (ed.) 2002.

influence on the reducing maternal mortality and the incidence of low birth weight children.

The World Health Organisation estimates that 80 per cent of the world's population from developing countries relies mainly on traditional medicines for primary health care. Of the 119 chemical compounds derived from 90 plant species, 74 per cent of these are used as drugs. The following Box 2 provides some information on the economic value of biodiversity to pharmaceuticals.

Environmental impacts leading to incidences of diseases like malaria and others are also recognised through MDGs. Box 3 below provides an example of the relationships between ecosystem disturbance and infectious disease.

Links to CBD

Under the CBD there is no specific Article that deals with issues of health or reducing mortality rates. However, the general principle of conservation and sustainable use of biological diversity is the focus for national action on using biodiversity to reduce the impacts of poor health on humans and ecosystems. Issues of ecosystem disturbance and related health impacts are receiving much attention.

Box 3: Diversity of vectors and pathogens

The major vector-borne pathogens and the diseases caused by them are concentrated in the tropics, with the majority of important vectors of human and animal diseases being found in the rich biodiverse tropical rain forest ecosystems, woodland savannas, and the edges of these ecosystems. The major insect vector groups – *Anopheles, Aedes, Culex,* and *Mansonia* mosquitoes; *Simulium* blackflies, the new world vectors of Leishmania (*Lutzomyia*); the *Chrysops* vector of Loa loa; and the *Glossina* species which transmit trypanosomes – all contain species which are dependent on forest, woodland savanna, or riverine forest ecosystems. It is the degradation of these ecosystems; the behaviour and ecology of the vectors at the forest edges; and the impact of reafforestation on the interactions between humans, vectors, and reservoir hosts at the boundaries between habitat types (ecotones) that determine the epidemiology of human infectious diseases. Additional factors are the degree of immunity of local or migrant populations; their nutritional status and their behaviour; the interaction with, and behaviour of reservoir hosts; and the availability and effectiveness of surveillance systems and healthcare.

Source: E. Chivian. (ed.) 2002.

Outputs from Asia regional workshop

Some of the more specific actions and interventions to achieve this MDG include:

Goal 2

- Strengthen primary health care and nutrition through the use of traditional knowledge and traditional medicine by identifying and encouraging the use of medicinal plants and crop plants to achieve house-hold and primary health care *e.g.* by documenting medicinal plants and use of a community (participatory) biodiversity register.
- Promote conservation of biodiversity through ecosystem approach for watershed management in order to ensure adequate water supply, in terms of quality and quantity, for households by developing appropriate management plans for watersheds and their use.
- Mitigate negative impacts of agricultural and forestry practices that affect child growth by developing suitable management methodologies for addressing issues of ecosystem imbalance and increases in incidence of diseases (e.g. clearing of forests and vector borne disease).

Goal 3

- Provide alternate sources of energy for household purposes for women by developing policies and mechanisms to replace existing methods of cooking and related activities.
- Promote forestry activities with a focus on sustainable harvesting and management of fuel wood and non-timber forest products by supporting activities such as Joint Forest Management and development of Community Wood lots, etc. (creating equitable access among gender, class and caste to forest resources).
- Promote innovative methods for using biodiversity as medicines by increasing support to research and development and raising awareness on medicinal plants and their usage.
- Promote agronomic practices that can provide better household nutrition by encouraging development of home gardens, Medicinal Plant Conservation Areas, mixed cropping, etc.

Goal 4

- Support ethnobotanical studies on role of plants/microbes in treating diseases by enhancing research and development and promoting the use of traditional medicine in treatment of such ailments.
- Promote option of using biological control agents by supporting research and development.
- Promote integrity of ecosystems by supporting initiatives such as land-use, capacity building, sharing of experiences.
- Promote management of water resources and bodies to achieve reduction in incidence of diseases by identifying and supporting appropriate management strategies.

2.4 Environmental sustainability and biodiversity

Goal 5 - Ensure environmental sustainability

Targets: Integrate the principles of sustainable development into country policies and programmes and reverse the loss of environmental resources; halve, by 2015,the proportion of people without sustainable access to safe drinking water; and achieve by 2020, a significant improvement in the lives of at least 100 million slum dwellers.

Current estimates are that approximately 1 billion people are affected by soil erosion and land degradation due to deforestation, overgrazing and agriculture. Water scarcity is a major issue in more than 20 developing countries. Over 2 billion people continue to rely on biomoss fuels and traditional technologies for cooking and heating and up to 2 billion people have no access to electricity (UNDP, UNDESA and World Energy Council 2000). Shortage of wood fuel imposes time and financial costs on poor households, putting a particular burden on those that are short of labour and making it harder for children to attend school.

Poor people are affected by natural resource degradation and biodiversity loss much more than the better off because of their limited assets and access. For example, in a study in West Africa, children showing growth abnormalities associated with poor nutrition (stunting) were found most frequently in areas of high soil degradation (GRID/Arendal 1997).

To understand the importance of biodiversity for human development, we need to evaluate the products that can be used and the economic system services that support human development. An accurate valuation of biodiversity needs to consider the direct use values (products) and indirect use values (services) and combine consumptive and non-consumptive use. The following Figure 3 explains some linkages.

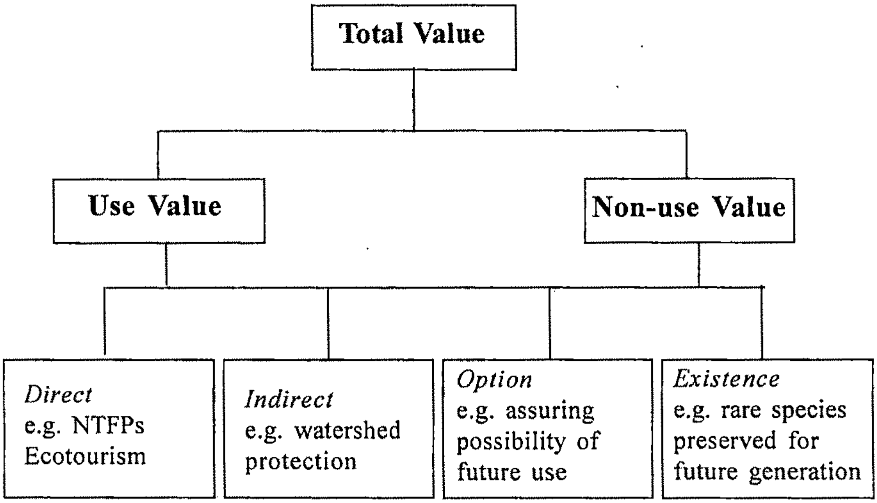
Apart from the direct use values, biodiversity found in ecosystems provide enormous economic gains. The following Table 2 illustrates some of these:

The underlying causes of biodiversity loss are very similar to the underlying causes of poverty and include centralized planning, constraints on access and ownership, unregulated markets, weak political voice, etc. The challenge for development here is to ensure that:

- biodiversity and the environment continue to provide goods and services needed for human development;
- costs and benefits from the use of such goods and services are sustainably and equitably shared;
- policies influencing sustainability are developed based on participatory approaches; and

- the scientific and technological impacts on services provided by biodiversity be assessed and solutions for ecosystem friendly alternative and efficiencies be found.

Figure 3: Economic value of biodiversity


Total Value
Use Value
Non-use Value
Direct e.g. NTFPs Ecotourism
Indirect e.g. watershed protection
Option e.g. assuring possibility of future use
Existence e.g. rare species preserved for future generation

Source: DFID, IUCN and EU 2000.

Table 2: Ecosystem services and functions

Ecosystem Service	**Estimated Economic Value (global, US$ ha/year)**		
	Wetland	**Forest**	**Rangeland**
Climate regulation		141	0
Disturbance regulation	4539	2	
Water regulation	15	2	3
Water supply	3800	2	
Soil formation		10	1
Erosion control		96	25
Nutrient cycling		361	
Waste treatment	4177	87	87
Pollination			25
Biological Control		2	23

Source: Constanza *et al.* 1997.

Improving environmental management to reduce poverty requires local understanding of how environmental conditions relate to poverty, and the ability to identify and set priorities on alternative policy options and evaluate their effectiveness and impact. Environmental data tend to focus on environmental change without determining poverty effects, while poverty monitoring systems often ignore environmental concerns. Indicators are therefore needed to measure health and vulnerability of the poor and these need to be integrated into national poverty monitoring systems and assessment.

Unfortunately, the Poverty Reduction Strategy Papers (PRSPs) fail to consider such issues and linkages. Greening PRSPs is thus the need of the hour. The "poverty-environment maps" available in few countries can be a good beginning point for such activities (Henninger and Hammond 2000).

Outputs from Asian regional workshop

The following specific actions may be considered to for mainstreaming issues of biodiversity in achieving MDG 7, in addition to those explained above:

- Integrate national action plans dealing with Convention on Biological Diversity, UN Framework Convention on Climate Change (UNFCCC) and the Convention to Combat Desertification (CCD) and their implementation.
- Identify monitoring mechanisms to achieve reduction of biodiversity loss (2010 targets) [Using indicators like threatened species].
- Promote ecosystem approach to conservation.
- Integrate biodiversity concerns into environmental impact assessments, strategic environmental assessments and others.
- Implement aforestation and reforestation programmes.
- Promote appropriate land use policies.
- Address issues of risk assessment and risk management with regard to genetically modified organisms and Invasive Alien Species.
- Creation and management of National Biodiversity Conservation Areas, Protected Areas and other areas of biodiversity hot spots and suggest appropriate actions to promote environmental sustainability.

- Link ecological sustainability with sustainable development (economic, social and environmental well-being).
- Achieve environmental sustainability through Clean Development Mechanisms (CDM), buffer zone management, eco-development plans and Joint Forest Management (JFM).
- Conjunctive use of water (surface and ground) for environmental sustainability.
- Support policies and plans for management of effluents to ensure environmental sustainability.
- Identify policies and interventions, where appropriate, to reduce out migration from rural areas by provision of employment opportunities.

Developing a global partnership and biodiversity

Goal 6 - Develop a global partnership for development

Targets: Develop further an open, rule-based, predictable, nondiscriminatory trading and financial system (includes a commitment to good governance, development and poverty reduction - both nationally and internationally);

Address the special needs of the least developed countries (including tariff- and quota-free access for exports, enhanced programme of debt relief for and cancellation of official bilateral debt, and more generous ODA for countries committed to poverty reduction;

Address the special needs of landlocked countries and small island developing states (through the Programme of Action for the Sustainable Development of Small Island Developing States and 22nd General Assembly provisions;

Deal comprehensively with the debt problems of developing countries through national and international measures in order to make debt sustainable in the long term;

In cooperation with developing countries, develop and implement strategies for decent and productive work for youth;

In cooperation with pharmaceutical companies, provide access to affordable essential drugs in developing countries;

In cooperation with the private sector, make available the benefits of new technologies, especially information and communications technologies.

Goal 6 of the MDGs focuses on means of achieving the first seven goals. In the spirit of this goal, developed and developing countries need to work in partnership to address sustainability issues.

The 1992 Earth Summit clearly established the objective of sustainable development. Ten years later this objective remains the goal of world community as stated through the Millennium Declaration and the MDGs. In addition, the Monterrey Summit on "Financing for Development" witnessed renewed commitments from developed countries to work towards meeting the ambitious targets for development. Achieving development goals requires considerable resources and creative use of both existing and new resources. Generating public resources and attracting private resources to finance development and conservation are thus needed.

Preliminary estimates by the World Bank are that it will take an increase in foreign aid of up to US$ 40 to 60 billion per year to reach the MDGs (Devarajan *et al.*, 2002). Increasing the quantity and effective delivery as well as use of aid is essential to ensure the poorest countries have resources to finance the investments required to reach critical thresholds in infrastructure, education and health. To ensure the effectiveness of the aid, developing countries need to improve economic and democratic governance and implement policies for effective poverty reduction. An example of inefficiencies and mismanagement, with drastic implications for development goals, is provided in Box 4. These issues must be overcome.

In addition to the increases in the Official Development Assistance, as promised at Monterrey, countries need to identify their own internal resources and move forward to forging new and better partnerships to mobilize more financial resources. Type 2 partnerships that bring about enhanced linkages between public and private sector; private sector and NGO; South-South cooperation as discussed at WSSD might be a way forward in addition to finding public-private partnerships.

Box 4:- Financial impact of energy mispricing in India

Power subsidies are imposing a growing and unsustainable financial burden in India. In 1992-93, total financial losses in the power sector came to US$ 1.7 billion. By 2001, low tariffs (which encourage high and wasteful use), high technical losses, and widespread non-payment, combined to increase state utility losses to more than US$ 5 billion per year. If current trends continue, state utility financial losses will reach US$ 10 billion per year in another three years. To put this magnitude of losses into perspective, US$ 5 billion is half of what all the state governments in India combined are spending on all levels of education every year. It is double what they are collectively spending on health, and three times what they are spending on water supply. If power sector financial losses were reduced by only one third, the savings in a single year would be sufficient to fill every teacher vacancy in the country and provide every school with running water and toilet facilities.

Source: IMF, UNEP and The World Bank 2002.

Debt relief can also help to release resources that could finance additional spending in areas that contribute to attaining the targets of the MDGs. That is, increased debt relief for developing countries will assist in creating an enabling environment for sustainable development. In addition, innovative ways for industrialized countries to provide assistance while promoting conservation should also be further explored. For example, debt for nature swaps can be an effective way of maintaining or promoting sustainable management of natural resources in developing countries in exchange for debt relief.

There is enormous scope for change to discriminatory trade policies in rich countries that limit market access for developing countries and distort global markets. It is recognised that greater market access for developing countries, coupled with development assistance, would significantly contribute to the likelihood of many countries achieving the MDGs by 2015 (Devarajan *et al.*, 2002). However, recent statistics indicate that current trade liberalisation rules and policies have lead to increases in poverty and inequality, with a disproportionately large negative impact on developing countries (World Trade Organization, 2003). Concerns regarding the current and emerging asymmetries in the world trading system should be addressed to ensure that the system evolves in such a way that it is responsive to the development needs of its members and that a more level playing field is created (RIS, 2003).

Technology transfer and benefit sharing are also key issues that affect people in developing countries and their path towards sustainable development. Technological innovations can increase productivity resulting in increased household incomes and provide solutions to many development problems such as disease, transport, energy, water supply and sanitation (UNEP, IISD, 2000; UNDP, 2003). It is vital that developed countries share technological progress with developing countries and invest more into technology development that addresses issues of poverty reduction. Recognition of indigenous knowledge, including knowledge about genetic material and technology, and benefit sharing for access to and use of this knowledge is also vital for meeting conservation and development goals as well as meeting the provisions of the CBD for the fair and equitable sharing of the benefits arising out of the use of genetic resources. These issues are summarised in the following extract from Walker (2001) (Box 5).

Conclusion

Achieving synergies between implementation of CBD, UNFCCC and MDGs is a key issue to achieve sustainable development. Agencies like Secretaries to Conventions, UNDP, UNEP and others have started thinking about bringing synergies to action. Specific and joint work programmes should be developed as a part of Joint Liaison Group and Ad Hoc Technical Expert Group. A specific inter-agency working group with a mandate to address synergies in action must be established and linkages to on-going ground work be developed. The Operational Programme 12 of the GEF explicitly encourages interventions aimed at considering an ecosystem approach. The ecosystem approach, adopted by the Parties to the CBD, aims to consider conservation actions through synergetic approaches. Encouraging Parties to submit innovative project ideas under the GEF's OP 12 dealing with ecosystem approach should be explored. Countries should be encouraged to specifically design programmes on synergies as a part of their national strategy and action plan.

Box 5: The TRIPS agreement and sustainable development: role of biodiversity and the CBD

- As the shift to a 'knowledge economy' continues, the definition of ownership and control of information becomes one of the most important policy issues facing societies. The leading international legal framework for determining rights over information is the World Trade Organization's (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (the TRIPS Agreement).
- This shift in the balance between public and private interests takes on a new dimension when viewed in the international context. Developed countries - which are traditionally home to the owners of formal technology - have tended to promote IPRs as beneficial to development. At times, developing countries by contrast - which are generally users, but not producers, of formal technology - have criticized IPRs, arguing that they raise prices and restrict access to the new technologies needed for sustainable human development. Despite bitter disputes between developed and developing countries during the Uruguay Round of trade negotiations, minimum standards for the protection and enforcement of IPRs were inserted on the international trade agenda in the form of the TRIPS Agreement.
- The TRIPS Agreement could also affect the transfer of technology under Multilateral Environmental Agreements. Research by the secretariats of the various MEAs suggests that IPRs present both opportunities and barriers to the transfer of environmentally-sustainable technology. While the role of IPRs in technology transfer should not be overstated, it is important that IP systems complement efforts to protect the environment by encouraging the transfer of environmentally-sustainable technology and minimizing the barriers that IPRs might pose to environmental protection. Yet the TRIPS Agreement remains essentially neutral to environmental concerns. Given the immediacy of environmental degradation, promoting the transfer of technology both through the TRIPS Agreement and MEAs is critical.
- In the area of health care and access to essential medicines, implementation of the TRIPS Agreement could help consolidate market control in the hands of a few pharmaceutical companies and increase the price of pharmaceuticals. This may pose serious health risks in cases where essential drugs are needed to respond to diseases such as HIV/AIDS, tuberculosis and malaria. According to the TRIPS Agreement, Members may adopt measures to protect public health and nutrition, including through the grant of compulsory licenses to local companies, as a means of promoting the public interest. Members, however, are often faced by unilateral pressure when seeking to operationalise these measures. Greater consideration needs to be given to the public health aspects of IPRs to ensure that the TRIPS Agreement promotes and does not undermine the right to health.

Source: Walker 2001

At the national level, the agencies coordinating implementation of the Conventions and Processes must establish a joint working group involving stakeholders and focal pints of the Convention to discuss options and actions. The Capacity Development Initiative (CDI) must address the issue of synergies specifically and all National Capacity Self Assessment (NCSA) activities must focus on this at national level. Agencies mandated to implement the Millennium Development Goals (MDGs) and WSSD outcomes (including those addressing WEHAB issues) must design processes on synergies soon, so that action of implementation can be inclusive.

At the local level, synergistic action should involve translating and scaling up local experiences into regional and national actions, development of replicatory models and influencing larger policy through action form the priorities. Initiatives like the Equator Initiative, Small Grants Programme of GEF have unique opportunities to identity such action and support replication and if need be improvement.

The key environmental agreements also contain many similar requirements for action, research, reporting and other necessary activities agreed by their signatories.

- Approaches to goals – The instruments adopt similar approaches to achieve their goals. They recognise needs for national action guided by international experiences. All of them recognise the need for capacity building and awareness rising as a pre-condition to their success. All of them also identify the need for cooperation.
- Approaches to activities - All of these instruments promote activities of research, assessments, information exchange, training, development of strategies and action plans and inventories. However, the decisions of design and detail are left open for interpretation by individual governments.

It is truism that we work in a world in which governments work primarily in a sector-based mode to develop and implement their policies and programmes. We need to bring in some changes to this scenario. Suggestion or recommendation for this include the following:

- Enhancing the institutional outlook
- Building capacities – both at personal and institutional levels
- Modifying National Planning processes
- Strengthening the information base.

Institutional outlook

With the overall framework of policymaking, planning and implementation of Rio Conventions and other Sustainable Development related policies, there are several core activities, which are particularly amenable to the issue of institutional synergies. These are:

- Awareness raising
- Education
- Reporting
- Data gathering and inventories
- Public participation
- Research and Training

To achieve these synergies it may be useful to consider the following options:

a) A crosscutting national committee to bring together key players - This is not new for several countries. National Planning Commission is a committee that brings together such players to decide on plans and budgets. Creation of a National Committee on Sustainable Development is an option.

b) Separate institutions with a coordinating mechanism - Several countries work on this principle at least in sectors like finance, banking and health. Similar model for environment may be an option.

c) A single institution responsible for all instruments – Many countries have Ministries of Environment and Natural Resources, which deal with several environment issues, but linkages within them are often weak.

At local level, some options include:

a) Creation of a coordinating committee representing all sectors

b) Making locally elected democratic institutions responsible for environment and development

c) Using groups and institutions like CBOs, Churches and Women's groups.

Building capacities

Capacity building and strengthening is urgently needed. Many countries are overtaxed by the competing demands and obligatory activities in addition to reporting requirements and monitoring.

Given this, it is important for countries to enhance their capacities. The GEF's Capacity Development Initiative (CDI) is a welcome option but falls short of addressing or supporting actual activities. Also, the implementation of CDI is in question due to the approval of only phase I of CDI by the GEF council where support is provided for National Capacity Self Assessments (NCSA) without clear emphasis on how countries can implement outcomes of NCSA. This makes CDI's use and effectiveness limited.

The general capacity needs to address synergistic activities include capacities on:

- Making inventories, monitoring and systematic observations.
- Planning, policy development and reform of legal frameworks.
- Impact assessment and research.
- Information, knowledge and data management.
- Reporting and monitoring.
- Education, Training and Public awareness.

Capacity building on these can be categorized to human resources, infrastructure development, coordination and cooperation.

Modifying national planning processes

Plans to implement the Conventions can foster synergies if they meet the following conditions:

1) Plans should be consistent with goals of national development.
2) Plans should identify the roles of the Conventions and other commitments at national, regional and global levels.
3) Plans should identify areas where overlaps and conflicts can occur and suggest means of turning them into opportunities of synergies.

Given this there are three possibilities to address national planning processes that can be responsive.

a) Develop separate plans for each agreement – Currently, this option receives both financial and political support that is neither effective nor suppressive of synergies. However, this should change.
b) Develop a new Umbrella Plan incorporating elements of all agreements – This is a good choice provided the institutional mechanism for planning and implementation are in place.
c) Develop a mechanism to integrate planning associated with the instruments into existing national plans and planning frameworks – This is the best option in the current situation but outlook and capacities to do so are weak.

Strengthening information base

Strong information systems, efficient networks and intelligent synthesis of these into knowledge equips a country to regularly assess the countries status and progress and plan for sustainable development. Implementation of all the agreements needs a good information base. Creation of this base with an implicit design for planning and monitoring is thus needed.

Countries and Conventions should also understand that information on its own merit is of little relevance for implementing activities. Information should be analysed and used in an integrated manner so that the information available through the clearing house mechanisms can be meaningful.

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Agricultural Biotechnology Sector in India: Issues Impacting Innovations

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Introduction

Agricultural biotechnology sector in India, particularly its plant biotechnology segment, is uniquely poised for a major process of transformation. As the country's agricultural biotechnology sector made strides in the 1990s in r-DNA, transgenics and molecular marker assisted plant breeding process, the Government of India responded with a matching policy support and regulatory framework that was designed to render the path of progress in R&D, sustainable and bio-safe. To a large extent, developments in the policy front have been induced by a vibrant non-governmental sector that intensely intervened on the sensitivities of modern biotechnology. This paper discusses analysis of the issues and proceeds to further consider the path of progress achieved by agricultural biotechnology companies in India in the area of commercialization of biotechnology products. The special focus of this paper is on plant biotechnology.

The biotechnology sector in India in 2002-03 is estimated to have attracted private investments to the tune of US$ 140 million. Infrastructure and R&D account for nearly 80 per cent of these investments.[1] During the period

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from 1986 to 2002 it is estimated that the Government of India invested an amount of US$ 275 million in the biotechnology sector. The Government of India has also extended venture capital support for biotechnology start-ups through the Technology Development Board and the New Millennium Indian Technology Industry Leadership Initiative (NMITLI). Meanwhile the States of Andhra Pradesh, Karnataka, Maharashtra, Gujarat, Kerala and Tamil Nadu have drawn up ambitious sub-national biotechnology policies, which promise fiscal and infrastructure support measures to prospective entrepreneurs. Some State Governments have launched their own venture funds for supporting novel start-up ventures.

To catalyse the process, the Government of India accorded priority to IPR protection. The Indian Patents Act of 1970 was amended to provide for product patents for agro-chemicals, drugs and pharmaceuticals and micro-organisms over a transitory period. A product patent regime would be in place in India by January 1, 2005. The new patent law extends protection term for inventions from 14 to 20 years. To provide for protection of IPRs in respect of new plant varieties, Parliament has enacted a *sui-generis* legislation in the shape of the Plant Varieties Protection and Farmers Rights (PVFR) Act in 2001. These developments have created favourable legal conditions for international partnerships in biotechnology R&D. By prioritizing FDI investments in biotechnology, the Government of India has sent appropriate signals to international investors. Further the fact that these changes have been in consonance with the WTO-TRIPs has lent greater creditability to these changes.

Meanwhile, the Government has also brought in regulations over agricultural biotechnology. Apart from the biosafety regulations that form part of the Environment (Protection) Act 1986, the Indian Parliament has legislated the National Biodiversity Act in the year 2002, to provide for regulatory controls over access to biological resources in India.

IPR Regimes for Plant Biotechnology

Article 27(3) of the TRIPs Agreement lays down that members shall provide for the protection of plant varieties either by patents or by an effective *sui-*

generis system or by any combination thereof. Article 27(3) in particular is critical to India as this requires us to provide protection of plant varieties by conferring plant breeders rights either by way of patents or through *sui-generis* plant variety protection legislations. Countries with strong R&D base in plant genetic engineering such as USA have robust Plant Utility Patent Legislations. India is certainly not inclined to adopt patent protection regimes for its plant varieties. India is rather inclined to adopt a *sui-generis* legislation which is non-'patent' based. There are many reasons for this proclivity. India is one of the ten mega-diversity countries of the world and a rich storehouse of landraces of principal agricultural crops. India has a strong R&D base in conventional plant breeding methods. Its strength in plant genetic engineering is impressive but not an overwhelming factor by comparison. The first two strengths explain India's disinclination towards plant patent regimes or towards a *sui-generis* legislation which is 'patent'-driven.

While Plant Utility Patents Act provide for broad patents over plant varieties, traits and genes and even the physical parts of the plants, plant breeders rights provide for IPR only over varieties. As is well known, since 1990s the UPOV (Union for the Protection of Varieties) has been largely viewed by developing countries as offering the best regime for positioning their national legislations.

The central feature of the UPOV is the protection it affords to plant breeders who produce plant varieties that fulfil the criteria of distinctiveness uniformity and stability (DUS). The current version of the UPOV, viz. UPOV 1991 had added additional criteria of 'new' to DUS thus rendering DUS as NDUS. Contrary to the popular notion, the NDUS criteria of UPOV 1991 is not substantively different from the principles of 'novelty', 'inventiveness' and 'industrial application' (NII) which applies for patents. The criteria of 'novelty' and 'inventiveness' in Patent Laws are covered by the criteria of 'new' and 'distinct' in UPOV 1991. Thus by distinctness, the UPOV means a variety of plant which is 'clearly distinguishable from other varieties whose existence is a matter of common knowledge'. It is apparent that this term captures the attributes of 'novelty' and 'inventiveness' implicit in Patent

Laws. Even in respect of 'uniformity' and 'stability' criteria the UPOV does not offer different recipes. True, by 'stability', the UPOV conveys that 'relevant characteristics of protected plant variety remain unchanged either for a specified period or after repeated propagations or cycles of propagations'. It is also true that 'stability' is a difficult criteria for a plant breeder to fulfil. Attainment of 'stability' criterion is problematic for cross-pollinated plants and non-single homozygous lines of autogamous plant varieties. This, in turn, reduces the commercialisation potential of the plant variety since inconsistency of genetic quality jeopardises commercial application of the plant variety. The same holds true of the criterion of "uniformity". Therefore, the NDUS criteria of UPOV 1991 are homologous to the NII criteria implicit in Plant Utility Patent Laws.

The UPOV has undergone two major amendments since its inception in 1961, i.e. in 1978 and 1991. The main concern with regard to currently operational UPOV 1991 has been its stringent provisions, which include the additional attribute of 'new' to the DUS criteria. The scope of UPOV 1991 in terms of coverage is larger. While plant varieties of all taxa are covered by UPOV 1991 only plant varieties of nationally designated species were covered by UPOV 1961 and 1978. Further by defining clearly that 'variety' represents a 'group of plants', or 'single' or 'several plants' or 'one' or 'several parts' of a plant(s) the UPOV 1991 has considerably enlarged the scope of its coverage. Going by this definition even sexual and vegetatively propagated varieties are covered by UPOV 1991. The US PVPA legislation has been quick to adopt the UPOV 1991 formula. The amendments of 1994 to the US, PVPA broadens the term 'plant varieties' to include all materials harvested from the protected varieties.

The other drastic feature of UPOV 1991 has been abridgement of the 'plant breeders exemptions' and 'farmers privileges' conferred by the earlier versions. Earlier versions of UPOV allowed farmers to re-use seeds generated from their farms for self-use, and allowed breeders to freely use protected varieties for further improvements. These concessions gave UPOV a 'less stringent' face in comparison to 'patent' laws. UPOV 1991 gives an option to National Governments to disallow the farmers privileges of retaining or re-using seeds for self cultivation. UPOV 1991 also restricts the breeders rights by enlarging the right of the breeder to close variations of his cultivar or 'essentially derived varieties'. In other words, the breeder of a cosmetically bred variety would have to buy genetic dependency rights from the derived variety prior to commercialising the derived version. Further the duration of protection have also been extended under UPOV 1991 to 20 years for crops and to 25 years for trees and vines. Thus in terms of these rigorous features, UPOV 1991 eliminates the arbitrage between plant varieties protection and patent regimes.

IPRs and investments in plant biotechnology

The implicit rationale for IPR protection is that they promote investments in plant breeding and bio-engineering. This hypothesis is contested by section of analysts. Nevertheless it is a fact that the structure of IPRs do influence investments. IPRs induce their own pattern of innovations. The time taken for R&D to fructify as innovations is a crucial aspect guiding investments. Often IPR regimes play a key role in influencing the time pattern of innovations.

It is a well-known fact that conventional plant breeding methods are dilatory and time consuming. It requires 7 to 8 generations of repeated breeding to reduce heterozygosity of new genotypes. As Vossen (1985) observes Arabica Coffee subject to three to four cycles of breeding still display heterozygosity and it is not until 20 to 25 years (spanning 4 to 5 generations) that one arrives at true breeding varieties. This time lag is even more pronounced for the Arabusta coffee variety (inter-specific hybrid of Arabica and Robusta Coffee) where segregation of unfavourable characteristics could still occur even after several generations of backcrossing and selfing.[2] Another interesting example is the one cited by Evenson (1991) about the long gestation period in regard to rice varieties in India. According to Evenson, India released 306 rice varieties for planting during the period 1965-1986 after performing 20,000 crosses over a period of over 15 years since 1950.[3] It must be understood that this long process of backcrossing was preceded by considerable time spent on location and identification of individuals plants with requisite traits. The speed or pace at which plant varieties qualify for being released for planting have economic implications on investment behaviour in seed/plant breeding industry.[4] Asexual modes of plant breeding which include plant genetic 'engineering' and transgenic techniques could obviate the long gestation period associated with pre-release preparations encountered conventional breeding.[5] It is a different matter than biosafety concerns may delay releases of these varieties.

The time lag in release of plant varieties fulfilling the criteria of novelty, distinctness, uniformity and stability (or alternatively the requirements of novelty, inventiveness and commercial application) raise fundamental issues from the view-point of capital investments. The time lag in varietal release is potentially least in the case of transgenic and non-sexually produced varieties while for traditional or classical methods the time lag can be greater.[6] The UPOV 1991 based plant IPR regimes could induce longer time lags as compared to the situation when an IPR regime is based on the 1978 version of the UPOV. This is due to the fact that the minimum genetic distance concept implicit in UPOV 1991 precludes 'close cousin' varieties from acquiring protection rights, unless the techniques of genetic distance determination by themselves are inadequate.

UPOV 1978 would facilitate capital investments to some extent as the release of plant varieties is periodically more frequent. Even under the plant patent regimes, investments could bring about short-term returns, though the volume of investments will have to be larger on account of capital intensity of advanced plant genetic engineering technologies. By comparison, UPOV 1991 regime is least conducive to capital investments as plant variety releases can be painfully slow under this regime. Therefore sustenance of conventional plant breeding under UPOV 1991 regimes, can only be ensured by infusion of low discount capital.

Paradoxically it is the reduced availability of low discount public funds for plant breeding that has induced countries like India to go in for Plant Varieties Protection Legislations modelled on UPOV lines. The implicit assumption in undertaking this step is that private funds for R&D in plant breeding will 'crowd in', if protection plant varieties rights are accorded. But the reality is that in liberalised deregulated developing economies, private investments have 'crowded in', in short return promising avenues.[7] In other words, private investment funds for R&D are not likely to be channellised into medium to long return yielding areas.

Let r_a, r_b & r_c be the discount rates relevant for regimes A, B & C in Figure I. Then the relative rates of discount will be

$r_1 > r_b < r_c$ [1]

and relative present worth will be

$p_a < p_b > p_c$ [2]

Consequently classical plant breeding activities will suffer for want of funds in the UPOV 1991. In other words, UPOV 1991 modelled national legislations will not necessarily hold attraction for private sector investors in R&D projects involving classical plant breeding as compared to say, UPOV 1978 or the Plant Patent regimes. Rather private investments would be catalysed better by *sui-generis* plant protection legislations, which partake of plant patent elements and focus in the main on hybrids and genetically engineered varieties.

Given the linkages between plant breeding and the seed industry these perverse investment behaviour trends can produce major economic consequences. The Seed Laws in various countries, both advanced and developing, are getting to be progressively oriented towards restricting market circulation to varieties that are conferred with plant breeder or patent rights. The UPOV guidelines on DUS are used world wide not only as the basis for establishing varietal distinctiveness and descriptions but also for seed certification purposes. The DUS guidelines are employed for recognising and registering not only the 'basic' seeds used for multiplication of 'pedigree' seeds but also for certification of the pedigree seeds themselves.[8] Evenson (1991) explains how absence of IPR rights will reduce Marginal Variable Costs (MVC) of seed multiplication. Tougher controls by certification of seeds could ensure that seed supply is kept in a 'constricted mode' and MVC of seed multiplication are raised. This in turn, will produce its own supply-demand dynamics as *Figure I* depicts.[9]

Figure I: Supply-demand dynamics for seeds in different IPR regimes

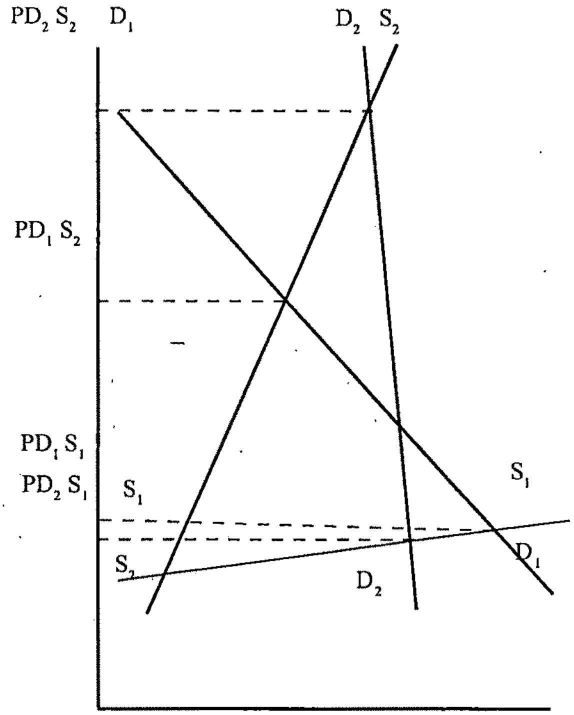

Figure I brings out the implications of IPR regimes in terms of the supply curves for seeds. As Figure I shows that in a situation of 'liberal' plant varieties protection laws (which do not provide for genetic distance) and equally liberal 'seed laws' which permit non-registered varieties (including landraces) to be sold in open markets, the macro-supply curve of seeds will be elastic (S1). When these regimes shift towards 'genetic dependency' PBR regimes and tighter seed laws that prohibit marketing of non-registered varieties, the supply curve will tend to be relatively inelastic (S2). Analogously, demand curves could shift from D1 (wherein demand for protected varieties will be elastic on account of availability of landraces and non-protected varieties in the markets) to D2 (where the demand for the protected variety will be inelastic on account of ban on sale of landraces and other non-protected varieties). In the D1-S1 situation, supply constraints and demand flexibility could induce low price regimes while in D2-S2 the reverse situation would occur. D2-S2 situation is not desirable for countries like India for other reasons as well. The experience of transitional economies of East Europe, which had re-modelled their Seed Laws in conformity with European Community Seed Laws, has been sad. Farmers of the East European bloc cultivating and conserving landraces have been adversely affected by new seed laws, which by prohibiting trade in non-registered varieties not fulfilling the DUS criteria have contributed to the erosion of landraces in these countries. It is thus clear that agro-biodiversity can be adversely affected by the uniformity criteria of DUS, which brings about resultant changes in demand and supply position of seeds.

Post R&D regulations and investments

Post-R&D regulations play a critical role in deciding on the pace of investments in the biotechnology sector. Even if a start-up enterprise enjoys a favourable IPR regime, that rewards its inventions, it is unlikely that it will invest in product development, in case post-R&D regulations are rigid and dilatory in nature. This then forms the backdrop for strategic alliances between start-up ventures and downstream industrial complexes.

Multi-layered regulations in the post-R&D phase involve complexities which are expressed in the delays in commercial application /utilization of invented products or technologies.[10] In the case of third generation plant biotechnologies, such as transgenics, the problem is compounded by the fact that regulations by themselves are complex and less understood by the regulators themselves.[11] A transgenic plant would have to undergo multi-stage regulatory checks and clearances before finding commercial application.

India is uniquely situated as far as biotechnology investments and infrastructure are concerned. In the area of plant biotechnology, advances have been made in transgenics of rice and wheat carrying stress tolerant genes such as CodA, COR47 and HVA1. The larger challenge is to take these products through the regulatory processes. More formidable is the issue of market development and appropriate pricing of transgenic seeds. There are many imponderables here. Market shares for seeds in India have varied from crop to crop and from region to region. The 'demand' for transgenic plants or seeds may be even more uncertain, given the 'safety' dimensions and risk aversion propensity of Indian farmers. In the dry agricultural pockets of Central and South India, farmers tend to be attached to traditional drought-hardy varieties of plants, which in turn contributes to their initial 'inertia' to shift to transgenics. Thus the task of marketing and pricing of novel biotechnology plants gets to be complex in such environment of 'demand incoherence'. A high margin pricing strategy for seeds may choke demand for transgenics. Thus the degree of risks in commercializing transgenic plants could be of a high order. Given these realities, the idea of strategic alliances between start-ups and downstream entities looks to be realistic. The fact that premier R&D institutions such as the Indian Institute of Science, has set up its own start-up biotechnology venture, renders a strategy of tie-ups, a logical option. Much will depend upon the complexities inherent in product development and the willingness of competent downstream entities to signup agreements. To a large extent, this will depend upon enabling policies at the upper end of the value chain.

To sum up, India's agricultural biotechnology industry has the necessary policy and regulatory support to promote active R&D. However, in the critical area of product development and commercialization much more attention needs to be paid. The multi-tiered regulatory framework that exists could seriously affect the performance of start-up companies that would like to run through the entire life-cycle of biotechnology product development. Consequently, partnerships and strategic alliances should be encouraged between start-up ventures and established companies that have high product development capabilities. The experience of other countries in the Asia Pacific region could be a key input in framing development strategies for biotechnology products in India.

Endnotes

[1] Anon, 2003.

[2] Vossen op.cit.

[3] Evenson op.cit.

[4] Damodaran, 1999a &b.

[5] Chrispeels, *et. al.*

[6] Damodaran, 1999a & b.

[7] Damodaran, 1999a&b.

[8] Kelly, Fenwick, A *et. al.*, 1998.

[9] Damodaran, 1999a&b.

[10] Damodaran, A.,. 1999a&b.

[11] Serageldin and Collins, 1999.

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Global Status of Commercialized Transgenic Crops: 2003*

Global Status of GM Crops in 2003

In 2003, the global area of transgenic crops continued to grow for the seventh consecutive year at a sustained double-digit growth rate of 15 per cent compared with 12 per cent in 2002. The estimated global area of GM crops for 2003 was 67.7 million hectares; this includes a provisional conservative estimate of 3 million hectares of GM soybean in Brazil (the final hectarage could be significantly higher), officially approved for planting for the first time in 2003. It is noteworthy that a double-digit rate of 10 per cent growth in GM crops was sustained in 2003, even excluding the Brazilian hectarage. The 67.7 million hectares of GM crops in 2003, equivalent to 167 million acres was grown by 7 million farmers in 18 countries, an increase from 6 million farmers in 16 countries in 2002. The increase in area between 2002 and 2003 of 15 per cent is equivalent to 9 million hectares or 22 million acres.

During the eight-year period 1996 to 2003, global area of transgenic crops increased 40 fold, from 1.7 million hectares in 1996 to 67.7 million hectares in 2003, with an increasing proportion grown by developing countries. Almost one-third (30 per cent) of the global transgenic crop area of 67.7 million hectares in 2003, equivalent to over 20 million hectares, was grown in developing countries where growth continued to be strong. It is noteworthy that the absolute growth in GM crop area between 2002 and 2003 was almost the same in developing countries (4.4 million hectares) and industrial countries (4.6 million hectares), with the percentage growth more than twice as high (28 per cent) in the developing countries of the South compared with the industrial countries of the North (11 per cent).

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* ISAAA Released this data on Cropbiotech Update Special Edition, January 14, 2004.

GM crop area, by country, crop and trait

In 2003, six principal countries, compared with four in 2002, grew 99 per cent of the global transgenic crop area; this reflects the broadening participation of the lead GM countries with ten countries now growing 50,000 hectares or more, of GM crops. The USA grew 42.8 million hectares (63 per cent of global total), followed by Argentina with 13.9 million hectares (21 per cent), Canada 4.4 million hectares (6 per cent); Brazil 3 million hectares (4 per cent), China 2.8 million hectares (4 per cent) and South Africa 0.4 million hectares (1 per cent). Of the six leading GM crop countries, China and South Africa had the highest year-on-year increase with a 33 per cent growth rate. China increased its Bt cotton area for the fifth consecutive year from 2.1 million hectares in 2002 to 2.8 million hectares in 2003, equivalent to 58 per cent of the total cotton area of 4.8 million hectares in 2003. South Africa increased its combined area of GM maize, soybean and cotton to 0.4 million hectares in 2003 with particularly strong growth in white maize used for food, which has increased rapidly from 6,000 hectares in 2001 to 84,000 hectares in 2003. Canada's GM crop area grew at a significant 26 per cent between 2002 and 2003 to reach 4.4 million hectares with increases totaling almost 1 million hectares in the three crops, canola, maize and soybean. Despite the continuing economic constraints in Argentina, and soybean adoption rates already close to 100 per cent in 2002, its GM crop area grew at 3 per cent with strong growth in Bt maize. A growth rate of 10 per cent was achieved in the USA (3.8 million hectares) reflecting strong growth in both Bt and herbicide tolerant maize, and continued growth in herbicide tolerant soybean. GM crop hectarage in Australia decreased slightly because of the continued severe drought, which is the worst in centuries, with total area planted to cotton at approximately one third of normal plantings. India increased its Bt cotton area by 100 per cent; Spain also increased its Bt maize area by one third to reach over 6 per cent of the national maize crop in 2003. Uruguay and Romania also reported significant growth, exceeding 50,000 hectares of GM crops for the first time, whilst countries that introduced GM crops for the first time in 2002, such as Colombia and Honduras reported modest growth.

Two countries, Brazil and the Philippines approved planting of GM crops for the first time in 2003. Brazil officially approved herbicide tolerant soybean in late September 2003, immediately before the start of the planting season. This late approval has exacerbated the difficulties in projecting provisional estimates of GM soybean hectarage in Brazil for the 2003/2004 season. At the time when this publication went to press, in late 2003, only 50 per cent of soybeans had been planted in Brazil. A provisional conservative estimate of 3 million hectares of GM soybean has been projected for Brazil in 2003, in the knowledge that the final planted hectarage of GM soybean in Brazil in 2003 could be significantly higher. The Philippines grew approximately 20,000 hectares of Bt maize for the first time in 2003. Brazil and the Philippines joined 16 countries that already grew GM crops in 2002 for a total of 18 GM crop countries in 2003; notably, 11 are developing countries compared with 7 industrial countries. Thus, the number of countries growing GM crops has increased steadily from 6 in 1996, to 9 in 1998, to 13 in 2001, and 18 in 2003.

Globally, in 2003, growth continued in all four commercialized GM crops: GM soybean occupied 41.4 million hectares (61 per cent of global GM area), up from 36.5 million hectares in 2002; GM maize was planted on 15.5 million hectares (23 per cent of global GM area), up substantially from 12.4 million hectares in 2002, with the highest growth rate for all crops at 25 per cent - this follows a 27 per cent growth rate in GM maize in 2002; transgenic cotton was grown on 7.2 million hectares (11 per cent of global GM area) compared with 6.8 million hectares in 2002; and GM canola occupied 3.6 million hectares (5 per cent of global GM area), up from 3.0 million hectares in 2002.

During the eight-year period 1996 to 2003, herbicide tolerance has consistently been the dominant trait followed by insect resistance. In 2003, herbicide tolerance, deployed in soybean, maize, canola and cotton occupied 73 per cent or 49.7 million hectares of the global GM 67.7 million hectares, with 12.2 million hectares (18 per cent) planted to Bt crops. Stacked genes for herbicide tolerance and insect resistance deployed in both cotton and maize continued to grow and occupied 8 per cent or 5.8 million hectares, up from 4.4 million hectares in 2002. The two dominant GM crop/trait combinations in 2003 were: herbicide tolerant soybean occupying 41.4 million hectares or 61 per cent of the global total and grown in seven countries; and Bt maize, occupying 9.1 million hectares, equivalent to 13 per cent of global transgenic area and grown in nine countries. Whereas the largest increase in Bt maize was in the US, growth was witnessed in all seven countries growing Bt maize. Notably, South Africa grew 84,000 hectares of Bt white maize for food in 2003, a substantial 14 fold increase from when it was first introduced in 2001. Bt/herbicide tolerant maize and cotton both increased substantially, reflecting a continuing trend for stacked genes to occupy an increasing percentage of the area planted to GM crops on a global basis.

A useful way to provide a global perspective of the adoption of GM crops is to express the global adoption rates for the four principal GM crops as a percentage of their respective global areas. In 2003, 55 per cent of the 76 million hectares of soybean planted globally were transgenic - up from 51 per cent in 2002. Twenty-one percent of the 34 million hectares of cotton were GM, up from 20 per cent last year. The area planted to transgenic canola in 2003 was 16 per cent, up from 12 per cent in 2002. Finally, of the 140 million hectares of maize grown globally, 11 per cent was GM in 2003 equivalent to 15.5 million hectares, up substantially from 9 per cent or 12.4 million hectares in 2002. If the global areas (conventional and transgenic) of these four principal GM crops are aggregated, the total area is 272 million hectares of which 25 per cent, up from 22 per cent in 2002, was transgenic in 2003. Thus, for the first time one quarter of the aggregate area of the four crops, totaling over one quarter billion hectares is GM. The biggest increase in 2003 was a 4.9 million hectares increase in GM soybean equivalent to a 13 per cent year-on-year growth, followed by a 3.1 million hectare increase in GM maize equivalent to a substantial 25 per cent year-on-year growth, which follows a 27 per cent year-on-year growth in 2002.

The potential contribution of GM crops

The World Food Programme recently reported that the number of people suffering from malnutrition increased by 25 million from 815 to 840 million. The most compelling case for biotechnology, and more specifically GM crops, is their capability to contribute to increasing crop productivity, and thus contribute to global food, feed and fiber security; conserving biodiversity, as a land-saving technology capable of higher productivity; more efficient use of external inputs, for a more sustainable agriculture and environment; increasing stability of production to lessen suffering during famines due to abiotic and biotic stresses; and, to the improvement of economic and social benefits and the alleviation of abject poverty in developing countries.

The experience of the first eight years, 1996 to 2003, during which a cumulative total of over 300 million hectares (approximately 750 million acres, equivalent to almost one-third of the total land area of the US or China) of GM crops were planted globally in 21 countries, has met the expectations of millions of large and small farmers in both industrial and developing countries. In 2003, coincidental with evidential confirmation that commercialized GM crops continue to deliver significant economic, environmental, and social benefits to both small and large farmers in developing and industrial countries, the global area of transgenic crops continued to grow at an annual sustained double-digit growth rate of more than 10 per cent. The number of farmers that benefited from GM crops continued to grow and reached 7 million in 2003, up from 6 million in 2002. Notably, more than 85 per cent of these 7 million farmers benefiting from GM crops in 2003, were resource-poor farmers planting Bt cotton, mainly in nine provinces in China and also in the Makhathini Flats in KwaZulu Natal province in South Africa.

The global value of GM crops

In 2003, the global market value of GM crops is estimated to be $4.50 to $4.75 billion, having increased from $4.0 billion in 2002 when it represented

15 per cent of the \$31 billion global crop protection market and 13 per cent of the \$30 billion global commercial seed market. The market value of the global transgenic crop market is based on the sale price of transgenic seed plus any technology fees that apply. The global value of the GM crop market is projected at \$5 billion or more, for 2005.

Concluding comments and future prospective

Despite the on-going debate in the European Union, there is cause for cautious optimism that the global area and the number of farmers planting GM crops will continue to grow in 2004 and beyond. Taking all factors into account, the outlook for the next five years points to continued growth in the global hectarage of GM crops to approximately 100 million hectares, with up to 10 million farmers growing GM crops in 25, or more, countries. The global number and proportion of small farmers from developing countries growing GM crops is expected to increase significantly. Established GM country markets are continuing to grow in GM area, with a more diversified portfolio of GM crop products available. New GM countries from the South, like India and Brazil, have increased their hectarage of Bt cotton and herbicide tolerant soybean respectively, and some like Uruguay have also approved new products such as GM maize, already deployed in other countries. New input trait products from industry that will contribute to sustained growth include the dual Bt gene (cry1Ac and cry1Ab) in cotton and two new traits introduced into maize in North America. The cry3Bb1 for corn rootworm control, and the cry1Fa2 gene in Bt maize, with broader control of lepidopteran pests were both introduced in the US in 2003. Furthermore, five new Bt and novel gene products for maize insect resistance are expected to be launched in the next three years. Thus, the global GM maize area with insect resistance and herbicide tolerance traits, as well as the stacked traits, is likely to increase significantly in the near to mid-term. With the approval of GM soybean in Brazil for 2003/04, global GM soybean area is likely to experience renewed high growth rates in the near to mid-term.

In 2003, the three most populous countries in Asia – China, India, and Indonesia (total population 2.5 billion and a combined GDP of over \$1.5

trillion), the three major economies of Latin America – Argentina, Brazil and Mexico (population 300 million and a GDP of $1.5 trillion) and the largest economy on the continent of Africa - South Africa (population 45 million and GDP of $130 billion) are all officially growing GM crops. Their combined populations of 2.85 billion with a total GDP of over $3 trillion are recipients of the significant benefits that GM crops offer. The top ten GM crop countries, each of which grew 50,000 hectares or more of GM crops in 2003, had a combined population of approximately 3 billion, close to half the world's population, with a combined GDP of $13 trillion, almost half of the global GDP of $30 trillion. In 2003, GM crops were grown in 18 countries with a combined population of 3.4 billion, living on six continents in the North and the South: Asia, Africa and Latin America, and North America, Europe and Oceania. Thus, despite the continuing controversy about GM crops, the hectarage and number of farmers growing GM crops have continued to grow at a double digit rate or more, every year since their introduction in 1996, with 7 million farmers benefiting from the technology in 2003.

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Outcome of COP Meeting

Efforts to promote the safety of international trade in genetically modified organisms received a new boost as a new system was adopted by the 87 member States of the Cartagena Protocol on Biosafety at a weeklong meeting in Malaysia attended by more than 1,000 delegates and observers. According to this, all bulk shipments of living or genetically modified organisms (known as LMOs, or GMOs) intended for food, feed or processing (such as soybeans and maize) are to be identified as "may contain LMOs." The accompanying documentation should also indicate the contact details of the importer, exporter or other appropriate authority. Environmentalists claimed victory over the United States. Although the new system is binding on countries that are party to the Protocol, many key agricultural producers, such as the United States, have not endorsed that pact.

The Cartagena Protocol, which entered into force last September, is designed to ensure the safe transfer, handling and use of GMOs that may adversely affect the conservation and sustainable use of biological diversity, taking also into account risks to human health. It forms part of the Convention on Biological Diversity negotiated under the auspices of the UNEP and signed by over 150 Governments at the 1992 Rio Earth Summit. Over the next year an expert group will further elaborate the documentation and handling requirements for bulk agricultural shipments. Key issues still to be resolved include the percentage of modified material that these shipments may contain and still be considered GMO-free and the inclusion of any additional detailed information. A decision on these matters will be considered at the next meeting of the treaty's Parties, to be held in 2005.

The US was quick to express its disappointment. "We understand the concerns that countries have to protect their biodiversity, but we believe you can't just erect walls and have regulatory procedures that are not based on science," biotech trade policy spokesperson Deborah Malac said. "Our biggest disappointment is that we feel they are moving down a path away from practical steps. They are moving very, very quickly in a direction without being sure parties can implement their obligations." The US is the world's biggest producer of GM crops and is already involved in a battle over export regulations in the World Trade Organization (WTO), where the EU wants strict labelling requirements.

Need to Develop Diotechnology Products Indigenously

The Union Secretary designate for the Department of Biotechnology, Dr M.K. Bhan, has said affordable and accessible biotechnology products should be developed indigenously, absence of which would only lead to increased socio-economic disparities. Addressing the inaugural session of the three-day global bio business forum - BioAsia - Dr Bhan said that biotechnology has huge potential to fulfil current societal needs by way of generating wealth and employment. The Government policies should be designed to drive investments into R&D and entrepreneurial infrastructure development. The State should also ensure uninterrupted support of academia-industry-market continuum and take the public-private partnership in R&D as far as it can go.

Investments in research by private sector must prioritise areas of maximum societal importance. Since there is need for communicating with public and policy makers and building a consensus on key issues such as genetically modified (GM) crops and foods, there should be an enabling environment for the biotechnology industry in the areas of intellectual property rights, infrastructure, tax incentives, simpler import of reagents, venture capital for new units and animal tests.

Transnational product movements would require similar and less complex regulatory processes and trade practices. Therefore, the initial successes in Asia were critical as these would encourage investments, public demand and enabling policies.

The Director-General of the Council for Scientific and Industrial Research (CSIR), Dr R.A. Mashelkar, said the country has already emerged as the global research and development centre and the world intellectual capital. More than 100 multinational companies have already set up their R&D centres in India and thousands of Indian professionals were returning back to homeland.

The agricultural scientist, Dr M.S. Swaminathan, advised the Andhra Pradesh Government to launch genetic literacy movement as a part of the Genome Valley aimed at reducing the genetic divide in the rural areas. He also asked the Government to establish a Rice Biotechnology Park in the Genome Valley and a National Resource Centre for effective dissemination of information pertaining to biotechnology. Towards this, interconnecting the Indira Gandhi National Open University (IGNOU), 11 State-based Open Universities and the recently should set up virtual university in the premises of ICRISAT.

Need to Focus on Socio-Economic Aspects of Biotechnology

Developing countries like India which the focus on social and economic concerns about genetically modified crops and technology were notable by their absence at the convention on bio-safety in Kuala Lumpur. Discussions at the Bio-safety Protocol meetings in Kuala Lumpur were not focusing on the social and economic aspects even though some country delegations including India, but specially the African Union had, flagged the issue," said Suman Sahai in a statement. She expressed anxiety that even developing country delegations negotiating the BSP have not given sufficient emphasis to this crucial clause, which has not come to the forefront of the discussions despite being part of the BSP (Article 26). She referred to the threat posed by genetically modified research in the west that is attempting to produce the characteristics of coconut and palm oil in the more common canola, a form of mustard.

Canola grows in temperate countries whereas coconut and oil palm is produced in the tropics. Many farmers in Asia earn a livelihood from the export of coconut and palm oil, both of which are sought after in the US and Europe for their special properties like high lauric acid content. Given the potential of genetically modified technology to damage the agricultural prospects of developing countries, the social and economic impact of the technology must be taken on board in the international agreements on bio-safety, through the Bio-safety Protocol.

India-US Grant to Promote Agriculture Sciences

India and the US Agency for International Development (USAID) have joined hands to award new grants to six universities for the promotion of agriculture sciences. The awards of up to $300,000 each would see forging of partnerships between colleges and universities in the US and India. The partnerships are designed to stimulate India's economic growth through revitalised agriculture, focusing on cutting-edge agricultural science and shared interests of the cooperating institutions and USAID. Five of the six grants are for south Indian universities.

Three of these are in Coimbatore in Tamil Nadu: Tamil Nadu Agricultural University's School of Postgraduate Studies, Agricultural Engineering College and Research Institute, and the Horticultural College and Research Institute.Two grants are for the University of Agricultural Sciences (UAS) in Bangalore and one is for the Punjab Agricultural University, Ludhiana. The collaborating US universities are Ohio State, Cornell, University of California, Davis, Purdue, Iowa and Michigan.

Such partnerships expand collaboration between the US and India, building on the transformed relationship between the democracies. The grant programme will help increase yield through new farming models and also improve post harvest management. The collaboration between Purdue University of US and the UAS in Bangalore will see efforts to educate people in rural areas about nutrition and enhance public awareness about the potential benefits of biotechnology in improving human nutrition. Similarly, the Ohio State University and the Punjab Agricultural University will collaborate to promote agricultural diversification and "add value" to raw food products through food processing to extend shelf life and explore export potential.

USAID and USDA to Promote Biotechnology

The US Agency for International Development (USAID) has issued a call for grant applications for research projects on the effects of agricultural biotechnology on biodiversity in developing countries. The projects will be funded through USAID's Biotechnology Biodiversity Interface (BBI) programme.

Grants, amounting to US$1.3 million, will be awarded for three- to four-year-long research programmes. Genetically modified (GM) crops, livestock, and fish have potential benefits. However, the safety concerns and their supposed effects on human health and biodiversity are also major issues that should be addressed. Further, the USAID stressed that although GM food safety studies conducted in the USA, Europe, and other developing countries are being conducted, studies on the interaction between the environment and GM crops should be dealt with on a case-to case basis since different countries have varied crop systems and species with which crops interact with.

French Farmers Oppose GMOs

Sixty six (66) per cent of French farmers are opposed to GMOs with most of them citing concerns over unknown risks and lack of information on the subject. These were the major findings of an opinion polling survey conducted by SNPAR in cooperation with the Institut d'études de marché et d'opinion (BVA). The survey was conducted with 400 farmers in France.

Results also showed that 50 per cent of the farmers would still not plant GM crops even if authorization will be given in the future by the French government. Sixteen per cent (16 per cent) also remained skeptical on the issue.

EU Decision on GM Maize in Council's Hands

The decision to authorize the import and processing of Monsanto's genetically modified (GM) maize known as NK603 has been referred to the Council of Ministers. This took place after the Regulatory Committee on the release of genetically modified organisms (GMOs) into the environment did not reach the qualified majority necessary to support the Commission's proposal.

The Commission will formally adopt the proposal. The Council of Ministers can either adopt or reject the proposal with a qualified majority. If no decision is made after three months, the proposal will then be returned to the Commission, who can then adopt it.

If authorized, this particular GM maize, which has been modified for increased tolerance to the herbicide glyphosate, would be labelled as GM. It will only be allowed for importation after April 18, 2004 - when the new European Union (EU) rules on GMOs enter into application, and after the authorization for food uses of NK603 have been granted as part of the new EU GM Food legislation.

Control of Flowering

Scientists from the Max Planck Institute for Plant Breeding Research in Cologne, Germany, and the Hebrew University of Jerusalem have recently demonstrated the molecular mechanism that plants adopt to trigger flowering in response to light duration and quality. Published in the February 13 issue of *Science*, the findings suggest the potential for control over flowering time and adaptation for growth under conditions different from natural habitats.

World food production from plants is mostly limited to specific seasons or certain regions of the world as plant species have unique precautions that trigger flowering only at the best time suited for its reproduction. The scientists conducted experiments on the model plant Arabidopsis thaliana (mouse-ear cress) to better determine the mode of regulation of light on flowering time. They demonstrated the effect of day length and light quality on the stability of a floral-promoting protein named constans. The latter explains why many plant species exhibit seasonal, day-length dependent flowering.

Arabidopsis is a small flowering plant commonly used as a model organism and is the first plant for which the whole genome has been sequenced.

Hebrew University researcher Dr. Alon Samach points out that flowering time manipulation could be achieved either through the introduction of genetic changes that could alter the stability of the floral promoter (constans) or through simple manipulation of sunlight elements.

White Biotechnology and Energy Management

The right choices in biotechnology may help overcome the growing pressure on the fossil fuels. Dr Wim Soetaert and Professor Dr Erick Vandamme from the University of Ghenton have released a report which offers a solution to the energy problems already on the horizon in the Europe. According to the report the EU is heading for an energy crisis while the solution is staring it in the face in the shape of industrial or 'white' biotechnology. It is also analyzed in the report that Brazil and the USA currently lead the way in the white technology sector. To this end the report calls for far more R&D investment for white biotechnology in the EU and a strategy for the future.

Many fossil fuels are expected to run out in 50 years and white biotechnology is being touted as a 'green' alternative for the future because it derives from renewable crops, rather than finite resources such as oil and coal. In the USA maize is used to produce energy – though in Europe sugar beet or wheat would be a more practical choice because they are more widely grown.

White biotechnology consists of making micro-organisms such as bacteria, yeasts or fungi react with each other to produce new substances. The basic principles have been understood for thousands of years and are involved in, for example, the production of beer, bread and wine. But only in the late 20th century did it become possible to speed up and perfect this process to obtain results that would never occur naturally. Vitamins and biodegradable plastics, as well as energy, can now be produced using white biotechnology. It is irrelevant to white biotechnology whether the raw materials it uses come from green biotechnology [GMOs] or not.

Syngenta Invests More for Plant Based Drug Research

The Syngenta has increased the investment in biopharming to an estimated $30 million in 2004 from a reported $12 million in 2002. Biopharming falls under the still murky category of genetic modification. Syngenta has taken the position that human and animal genes in plant biotechnology could open up new medical paths, but has stressed that none of its genetically modified crops so far use human or animal genetic material.

In this regard the collaboration between Syngenta and Diversa Corporation is being seen with great interest. They have a number of joint research programmes, including a joint venture to develop animal feed additives and formulations, and a discovery programme focused on altering genes in crops. Syngenta has also acquired an ownership stake in Diversa which is estimated at about 18 per cent. Under a seven-year, $118 million deal that began in 2003, Syngenta and Diversa have combined their biopharma research activities in genomics and selected antibody generation. Diversa reported in January that it received milestone payments of $1.7 million as part of its Syngenta joint venture, called Zymetrics. The payments were reportedly triggered by Diversa's delivery of several product candidates for feed and food processing applications, and the regulatory approval of Zymetrics' Quantum Phytase animal feed enzyme in Mexico. Quantum, designed to improve how chickens and pigs absorb nutrients from their food, is awaiting a potential marketing approval from the U.S. Food and Drug Administration.

Eastern Europe Struggles with the GM Policy

As in many other developing countries the commercial approval of GM crops in Eastern Europe also faces several policy challenges. There are some 13 countries in the region which are the leading candidates for the EU enlargement. They are Bulgaria, Malta, Cyprus, Poland, Czech Republic, Romania, Estonia, Slovakia, Hungary, Slovenia, Latvia, Turkey and Lithuania.

In this regard Bulgaria has become an extremely interesting case. There a draft law on GM organisms which was submitted to Parliament for the first time in 2000. The government proposal, however, was blocked because of a lack of clarity on mechanisms to control GM produce. At the time, three companies submitted applications to be allowed to commercialise transgenic plants - Monsanto, Pioneer and Novartis. Initially there was some resistance but later it was found that some of the farmers have already grown genetically modified corn that was used to feed animals. Meanwhile, in Bulgaria USDA organized the first national biotechnology conference in Sofia in collaboration with the Bulgarian Biotechnology Information Centre. This brought in experts from all over the world to discuss the various fields of agricultural biotechnology. The biotech conference also coincided with the passing of the genetically modified organism (GMO) law in the Bulgarian Parliament.

It is interesting to watch that some of the countries in the East of Europe, such as Ukraine, Romania and Bulgaria, which want to join the Union in 2007 have been engaged in growing of GM crops. Romania, anxious to please the US, has grown GM crops on a large scale. Neighbouring Serbia accuses Romania of contaminating its supposedly GM-free crops as a result of grain smuggling across the border. After the debates in Bulgaria's Parliament on the new law on genetically modified organisms, many MPs expressed concern that legalising GM foods is only being done to benefit multinational companies, like Monsanto and Pioneer, which anyhow have been present on the Bulgarian market for years.

In the meantime, Bulgaria has been a battlefield in the war between seed producers like Monsanto and Pioneer, and food processors and traders that do not want to, and in any case cannot, sell GM foods to the European Union. According to the environmentalist movement Ekoyugozapad (EcoSouthEast), Bulgaria has become "the grass that the two elephants are trampling, while bickering for the control over the GM foods".

In a story the London based *The Guardian* has pointed out that these countries do not have the testing facilities to monitor the spread of GM crops to neighbouring countries. The problem is not lack of legal regulation. The EU has ensured that all the new members have rules on GM similar to those in the rest of the community. The difficulty is enforcement. The biggest agricultural country in eastern Europe, Poland, which has been growing

GM crops for several years, has had no testing facilities at all. Some GM crops had been approved in the EU. If a food product contained more than 0.9 per cent of an approved GM crop then it would have to be clearly labelled. Products containing more than 0.5 per cent of crops - such as GM potatoes - that were not approved in the EU would have to be labelled as containing GM ingredients.

This second provision is an added hurdle for some of the 10 new member states because they have been growing crops not yet approved in the EU. Some of these may never be approved because they have been superseded by other varieties and have fallen out of fashion.

(***Source:*** RIS based on *Crop Biotech Update*, February 20, 2004; *Check Biotech* January 16, 2004; *Check Biotech* February 20, 2004; *Check Biotech* February 20, 2004; Paul Brown, environment correspondent February 14, 2004 *The Guardian*; Indo-Asian News Service February 26, 2004; *The Hindu Business Line*, February 26, 2004; Jasano Media)

Working Group I

Mountain biodiversity

Final Decision: In the decision (UNEP/CBD/COP/7/L.29), the COP adopts the annexed work programme on mountain biodiversity, invites Parties to adopt outcome-oriented targets, and encourages governments to enter into partnerships in order to address the need for resources, human, technological and financial capacity to implement the work programme. The COP requests the Executive Secretary to: develop proposals on a small number of global outcome-oriented targets and timeframes relating to the 2010 target; and collect and share information about the role of mountain ecosystems in producing and maintaining freshwater resources, and about the consequences of climate change and desertification on mountain biodiversity.

The annexed work programme contains elements on direct actions for, means for implementing and supporting actions for conservation, sustainable use and benefit-sharing. Element 1: establishes goals to:

- prevent and mitigate the negative impacts of key threats to mountain biodiversity;
- protect, recover and restore mountain biodiversity;
- promote the sustainable use of mountain biological resources;
- promote ABS; and
- maintain genetic diversity in mountain ecosystems, in particular through preserving and maintaining traditional knowledge and practices.

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[*] Key decisions taken at the Seventh Conference of Parties to the Convention on Biological Diversity (CBD) which was held in Kuala Lumpur, Malaysia from the February 9-20, 2004.

Element 2 sets goals to:

- enhance the legal, policy, institutional, and economic framework;
- respect, preserve, and maintain traditional knowledge; and
- establish regional and transboundary collaboration.

Element 3 establishes goals to:

- develop work on identification, monitoring and assessment;
- improve knowledge on, and methods for, assessing and monitoring the status of mountain biodiversity;
- improve the infrastructure for accurate assessment and monitoring and develop associated databases;
- improve research, technical and scientific cooperation, and other forms of capacity building;
- increase public education, participation and awareness; and
- promote the development, validation, and transfer of appropriate technologies for mountain ecosystems, including indigenous technologies in accordance with Article 8(j).

Protected Areas

Final Decision: The final document (UNEP/CBD/COP/7/L.32) contains a decision and an annexed work programme.

In the decision, the COP:

- recognizes that the work programme should be implemented in the context of nationally determined priorities, capacities and needs;
- emphasizes: the need for capacity building in developing countries; and that the targets included in the work programme provide a framework within which national and/or regional targets may be developed, and activities prioritized according to national priorities and capacities; and
- underlines the importance to conserve biodiversity not only within but also outside PAs.

The COP calls on Parties to estimate the cost of implementing the necessary activities to meet the targets of the work programme and report back to

COP-8, and integrate PA objectives into their development strategies. Parties are further invited to consider options, such as ecological networks, ecological corridors, buffer zones and other approaches.

The COP requests the GEF to support the implementation of the work programme through various specific actions.

Regarding the work programme's overall objective, the COP adopts the annexed work programme with the objective of establishing and maintaining by 2010 for terrestrial areas, and by 2012 for marine areas, effectively managed and ecologically representative national and regional PA systems that contribute, through a global network, to achieving the three objectives of the Convention and the 2010 target. A definition of global network is footnoted.

The COP further:

- notes that the establishment, management and monitoring of PAs should take place with the full and effective participation of, and full respect for the rights of, indigenous and local communities consistent with national law and applicable international obligations;
- urges Parties to elaborate outcome-oriented targets; and
- decides to: establish an ad hoc open-ended working group on PAs to support and review implementation of the work programme; and assess progress in the implementation of the work programme at each COP meeting until 2010.

The Executive Secretary is requested to, *inter alia*, make arrangements to hold at least one meeting of the working group before COP-8.

The work programme consists of four programme elements, which contain goals, targets and suggested activities for the Parties and the Executive Secretary. Element 1 sets goals to:

- establish and strengthen national and regional PA systems integrated into a global network;
- integrate PAs into broader land- and seascapes and sectors;

- establish and strengthen regional networks, transboundary PAs and collaboration between neighboring PAs across national boundaries;
- substantially improve site-based PA planning and management; and
- prevent and mitigate the negative impacts of key threats to PAs.

Element 2 sets goals to:

- promote equity and benefit-sharing; and
- enhance and secure involvement of communities and relevant stakeholders.

Element 3 sets goals to:

- provide an enabling policy, institutional and socio-economic environment for PAs;
- build capacity for the planning, establishment and management of PAs;
- develop, apply and transfer appropriate technologies for PAs;
- ensure financial sustainability of PAs and national and regional systems of PAs; and
- strengthen CEPA.

Element 4 sets goals to:

- develop and adopt minimum standards and best practices for national and regional PA systems;
- evaluate and improve the effectiveness of PA management;
- assess and monitor PA status and trends; and
- ensure that scientific knowledge contributes to the establishment and effectiveness of PAs and PA systems.

Strategic plan

Final Decision: In the decision (UNEP/CBD/COP/7/L.27), the COP recognizes the need to facilitate assessing progress towards the 2010 target, provide a flexible framework within which national and regional targets may be set, and establish a mechanism to review the Convention's implementation.

The COP decides to develop a framework to enhance the evaluation of achievements and progress in implementing the Strategic Plan, and agrees that a limited number of trial indicators be developed. The COP requests SBSTTA, with the assistance of an ad hoc technical expert group (AHTEG), to review the use of annexed indicators and develop additional ones. The COP requests the Working Groups on ABS and on Article 8(j) to explore the need and options for indicators for ABS.

The COP establishes goals and sub-targets to, *inter alia*, help assess progress towards the 2010 target, and promote coherence among the Convention's work programmes. It requests SBSTTA to refine proposals for integrating outcome-oriented targets into work programmes on inland water ecosystems and on marine and coastal biodiversity, and requests the Executive Secretary to prepare proposals for integrating goals and targets into the work programmes. The COP emphasizes the need for capacity building, and invites Parties, governments, and organizations to provide adequate and timely support for implementation.

The COP decides to allocate adequate time in subsequent COP, SBSTTA and Working Group meetings, and establishes an ad hoc open-ended Working Group on Review of Implementation of the Convention.

The decision includes three annexes, containing: provisional indicators for assessing progress towards the 2010 biodiversity targets; a provisional framework for goals and targets; and a general approach for integrating targets into the work programmes.

Thematic programmes of work

Forest biodiversity

Final Decision: In the decision (UNEP/CBD/COP/7/L.13 A), the COP recommends incorporating relevant indicators into the work programme. It encourages regional-level cooperation, and invites enhancement of cross-sectoral integration and inter-sectoral collaboration. The COP also requests the Executive Secretary to: propose outcome-oriented targets to be integrated into the work programme; continue collaborating with other members of the CPF on harmonizing and streamlining national reporting; and facilitate the full and effective participation of indigenous and local communities and other relevant stakeholders.

Dry and sub-humid lands

Final Decision: In the decision (UNEP/CBD/COP/7/L.13 B), the COP adopts a process for the periodic assessment of the status and trends of biodiversity of dry and sub-humid lands, and welcomes the joint work plan between the CBD and UN Convention to Combat Desertification (UNCCD). The decision requests the Executive Secretary, in consultation with Parties, to develop targets for implementation and, in collaboration with the Secretariats of other relevant conventions, to facilitate their synergistic implementation. It also urges Parties and relevant stakeholders to provide the necessary support

Agricultural biodiversity

Final Decision: In the decision (UNEP/CBD/COP/7/L.13 C), the COP takes note of the report of the AHTEG on GURTs, and requests its consideration by SBSTTA-10. It invites mainstreaming agricultural biodiversity into national plans and strategies, with the active participation of indigenous and local communities, and invites NGOs to assist Parties to build capacity to this end. The decision also requests the Executive Secretary to invite the FAO and other relevant organizations to address agricultural biodiversity, and urges ratification of the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGR).

Inland and water ecosystems

In the decision, the COP encourages synergies between the CBD and the Ramsar Convention on Wetlands, and recognizes the need for human, technological and financial resources, and for reliable baseline data and regular national assessments of inland water biodiversity. The COP requests the Executive Secretary to develop, with the Secretariat of the Ramsar Convention, a proposal on streamlining national reporting. It urges Parties to incorporate the objectives and relevant activities of the work programme in their biodiversity strategies by 2005, and to share information and lessons learned from the application of national and regional policies. The COP invites Parties to formulate and adopt outcome-oriented targets for each activity, including timescales, and requests SBSTTA to review Ramsar's interim classification system.

The work programme consists of goals, objectives and activities grouped under three programme elements.

Element 1 on conservation, sustainable use and benefit-sharing contains goals on: integrating the conservation and sustainable use of biodiversity into all relevant sectors of water resource and river basin management; establishing and maintaining comprehensive, adequate and representative systems of protected inland water ecosystems; enhancing the conservation status of inland water biological diversity; and addressing IAS.

Element 2 on the institutional and socio-economic enabling environment contains goals on: promoting the integration of conservation and sustainable use of inland water biodiversity into existing programmes and legislation, promoting technology and innovative approaches; providing incentives and valuation measures to support the conservation and sustainable use of inland water biodiversity, and to remove any perverse incentives; implementing the work programme for the Global Initiative on CEPA; and promoting participation.

Element 3 on knowledge, assessment and monitoring contains goals on: developing an improved understanding of inland water ecosystems; developing an improved understanding of threats to inland water ecosystems; performing impact assessments on projects and actions that might negatively affect inland water biodiversity, including cultural, environmental, and socioeconomic impact assessments, in accordance with the Akwé: Kon guidelines; and introducing and maintaining appropriate monitoring arrangements.

Marine and coastal biodiversity

Final Decision: The decision (UNEP/CBD/COP/7/L.31 and Add.1) contains sections on: the review of the work programme on marine and coastal biodiversity; MCPAs; assessment, monitoring and research priorities; mariculture; deep seabed genetic resources beyond national jurisdiction; and conservation and sustainable use of biodiversity in marine areas beyond the limits of national jurisdiction. The decision includes annexes on: the elaborated work programme; guidance for national marine and coastal biodiversity management frameworks; and data for assessing progress towards the global goal.

In the decision, the COP:

- agrees that the work programme should: be applied in accordance with national law, and where applicable, international law, including UNCLOS; and address issues related to biodiversity and climate change;
- extends the time period of the work programme by an additional six years; and
- notes the adoption of the International Maritime Organization's International Convention for the Control and Management of Ships' Ballast Water and Sediments.

Regarding MCPAs, the COP agrees:

- that the goal for work related to MCPAs under the Convention should be the establishment and maintenance of MCPAs that are effectively managed and ecologically based, and that contribute to a global network of MCPAs, building upon national and regional systems, and including a range of levels of protection;
- to develop a strategy to meet WSSD goals related to the conservation and management of oceans; and
- that full indigenous and local participation is important for achieving the global goal and for the establishing and maintaining MCPAs.

Parties are urged to adopt wider marine and coastal management frameworks taking into account the appended elements.

Regarding MPAs beyond national jurisdiction, the COP recognizes that the law of the sea provides a legal framework for regulating activities, and requests the Executive Secretary to collaborate with the UN Secretary General and relevant bodies to identify mechanisms to establish and manage such MPAs.

Regarding international support for the creation of networks of MCPAs, the COP urges financial and technical support to establish a global system of MCPA networks, including identification and removal of barriers to their creation and removal of perverse incentives for unsustainable activities.

Regarding mariculture, the COP takes note of the negative and some positive effects of mariculture on biodiversity. The COP urges Parties to adopt: relevant techniques, some of which are listed in the decision, to avoid the adverse effects of mariculture; and relevant best management practices and legal and institutional arrangements for sustainable mariculture.

On conservation and sustainable use of deep seabed genetic resources beyond national jurisdiction, the COP requests the Executive Secretary to compile information on methods for identifying, assessing and monitoring deep seabed genetic resources, and report to SBSTTA. Parties are invited to identify activities and processes under their jurisdiction or control, which may have a significant adverse impact on deep seabed ecosystems and species beyond national jurisdiction.

Regarding conservation and sustainable use of biodiversity in marine areas beyond the limits of national jurisdiction, the COP calls on the UN General Assembly and other relevant organizations to urgently take measures to eliminate/avoid destructive practices, including the application of precaution and consideration of interim prohibition of destructive practices.

The elaborated work programme contains sections on: its vision, mission, goals and targets; basic principles; programme elements on integrated marine and coastal area management (IMCAM), marine and coastal living resources, MCPAs, mariculture, IAS, and general matters; enabling activities; and a time schedule. The work programme contains five appendices on: a work plan for coral bleaching; elements of a work plan on coral reefs; elements of a marine and coastal biodiversity management framework; research priorities for MCPAs; and research and monitoring priorities for mariculture.

Monitoring and indicators

Final Decision: In the decision (UNEP/CBD/COP/7/L.11), the COP, *inter alia*:

- requests SBSTTA to review the findings of the MA;
- recognizes the need to strengthen the scientific base for decisions;
- urges Parties and other governments to contribute case studies on experiences with environmental impact assessments (EIA) and strategic environmental assessments;
- encourages increased collaboration between the CBD and other conventions and organizations;
- encourages bilateral and multilateral funding agencies to assist developing countries and countries with economies in transition; and
- requests the CHM to develop an effective system of information sharing.

Biodiversity and climate change

Final Decision: In the decision (UNEP/CBD/COP/7/L.16), the COP invites Parties to use the report of the AHTEG on Biodiversity and Climate Change to promote synergies between the CBD and UNFCCC. The COP notes that climate change mitigation and adaptation activities can be implemented in ways that are mutually beneficial, and that the ecosystem approach provides a framework for the integrated management of land, water and living resources. The COP invites financial support to developing country Parties, and requests the Executive Secretary to gather relevant material for promoting synergy between climate change mitigation and adaptation activities, and the conservation and sustainable use of biodiversity.

Global taxonomy initiative

Final Decision: In the decision (UNEP/CBD/COP/7/L.12), the COP invites Parties to support taxonomic initiatives to attain the 2010 target, provide all necessary support to taxonomic centers of research and expertise, and appoint national focal points. The COP urges Parties and the GEF to provide support to developing countries, and invites developed country Parties to support the GTI's Coordination Mechanism. The COP requests: Parties to report on the status of implementation of the GTI work programme; and the Executive Secretary to develop guidelines for in-depth review, undertake gap analyses regarding the taxonomic components of the existing work programmes, and facilitate synergistic cooperation between existing initiatives.

Global strategy for plant conservation

Final Decision: In the decision (UNEP/CBD/COP/7/L.15), the COP encourages Parties to nominate focal points, and requests the Executive Secretary to develop a toolkit to assist Parties in integrating the GSPC targets into their strategies. The COP decides to integrate the GSPC targets into the CBD's thematic and relevant cross-cutting work programmes, and into the reporting framework for the third national reports.

Ecosystem approach

Final Decision: In the decision (UNEP/CBD/COP/7/L.14), the COP calls on Parties to implement the ecosystem approach, noting that the guidelines need to be considered as voluntary instruments, adapted to local conditions and implemented in accordance with national legislation. It notes that SFM, ecosystem based management, integrated river basin management, integrated marine and coastal area management and responsible fisheries approaches may support implementation of the ecosystem approach. The COP requests the Executive Secretary to, *inter alia*, identify gaps in the coverage of existing tools and approaches, and recommends that Parties provide feedback on their experiences, share their expertise, and promote better understanding of the ecosystem approach. The decision includes annexes on the refinement and elaboration of the ecosystem approach, and consideration of the relationship between SFM and the ecosystem approach.

The implementation guidelines contained in Annex I relate, *inter alia*, to:

- decentralizing management;
- considering the effects of ecosystem management on adjacent ecosystems;

- managing ecosystems in an economic context;
- prioritizing the conservation of ecosystem structure and functioning;
- managing ecosystems within the limits of their functioning;
- setting long-term objectives to ecosystem management;
- seeking the appropriate balance between biodiversity conservation and management;
- considering all forms of relevant knowledge, including scientific and indigenous knowledge; and
- involving all sectors of society and scientific disciplines.

Annex II defines the conceptual basis of the ecosystem approach in relation to SFM, outlines proposals for integrating the ecosystem approach with SFM, and addresses the integration of the ecosystem approach into sectors and biomes corresponding to the Convention's thematic programmes

Sustainable use

Final Decision: In the decision (UNEP/CBD/COP/7/L.17), the COP stresses the interlinkages between the Addis Ababa Principles and Guidelines for Sustainable Use and the ecosystem approach, which it identifies as the primary framework for action under the CBD. It recognizes the need to further elaborate the Principles and Guidelines, specifically with respect to domesticated species, breeds and varieties in the context of the work programme on agricultural biodiversity, and emphasizes the need for technology transfer and cooperation, and for capacity building.

The COP, *inter alia*, invites Parties to implement the Addis Ababa Principles and Guidelines at the national and local levels, taking into account obligations under other international agreements and existing frameworks of sustainable use. It requests SBSTTA to explore the applicability of the Principles and Guidelines to agricultural biodiversity, prior to COP-9.

The COP requests the Executive Secretary to:

- collect information and experiences on success stories, best practices and lessons learned;
- undertake further work on the use of terms for sustainable use, adaptive management, monitoring and indicators; and

- convene a series of technical experts workshops on ecosystem services assessment, financial costs and benefits of biodiversity conservation, and sustainable use of biological resources; and
- invite further research, transfer of technologies and financial support to assist in the implementation of the Principles and Guidelines at the national level.

The decision contains two annexes: a note on sustainable use, prepared for SBSTTA-9, and the Addis Ababa Principles and Guidelines.

Biodiversity and tourism

Final Decision: In the decision (UNEP/CBD/COP/7/L.10), the COP adopts the annexed guidelines, notes their voluntary nature, and requests the Executive Secretary to develop a user manual and checklist, and make available a streamlined and user-friendly core set of improved voluntary guidelines. The COP emphasizes consistency with the Akwé: Kon Guidelines, and invites Parties to provide indigenous and local communities with capacity building and financial resources to support their active participation in tourism policy making. The COP calls for additional efforts to increase awareness on the Guidelines, and invites the Executive Secretary to report on progress made in their implementation and improvement.

The annexed guidelines consist of four parts regarding: scope; the policy making, development planning and management process; notification process and information requirements; and education, capacity building and awareness raising.

Invasive alien species

Final Decision: In the decision (UNEP/CBD/COP/7/L.18), the COP notes the adoption of the International Convention for the Control and Management of Ships' Ballast Water and Sediments, and requests the Executive Secretary to promote fuller consideration of issues relating to IAS in other international fora, and further collaborate with relevant organizations and initiatives. It invites the WTO to give consideration to risks from IAS in its deliberations, and requests the Executive Secretary to collaborate with the WTO

Secretariat to raise awareness on IAS-related issues, and renew his application for observer status in the WTO SPS Committee.

The COP invites Parties and organizations to, *inter alia*: improve coordination of regional measures to address transboundary issues; support national and regional decision-making; incorporate IAS considerations into regional agreements; allocate adequate financial resources to developing countries; and consider the introduction of positive incentive measures. It is noted that implementation of the paragraph on incentive measures should not promote incentives that negatively affect biodiversity of other countries.

The COP notes specific gaps in international regulatory frameworks and the potential for application of existing methodologies for assessment and analysis, and requests SBSTTA to establish an AHTEG to address these gaps and inconsistencies.

It requests the Executive Secretary to: address the priorities for practical actions identified in the COP decisions; and facilitate the development of practical processes to allow Parties to share best practices and lessons learned. It invites the GEF and other institutions to provide support to developing countries.

Working Group II

Technology transfer

Final Decision: In the decision (UNEP/CBD/COP/7/L.20), the COP adopts the annexed work programme on technology transfer and technological and scientific cooperation, and:

- decides that implementation of the work programme should be undertaken in close coordination with relevant activities of the Convention;
- invites Parties to convene national, subregional and regional workshops to exchange information and enhance capacity;
- requests the Executive Secretary to convene the informal advisory committee of the CHM to assist the Executive Secretary with

providing advice on the CHM's possible role as a central mechanism for information exchange and facilitation of technology transfer;
- requests the Executive Secretary to establish an expert group on technology transfer and scientific and technological cooperation to assist with preparing proposals on measures and mechanisms to facilitate access to, and adaptation of, technologies;
- invites Parties' development of innovative approaches and means of technology transfer and cooperation;
- urges financial and technical support and training to assist in the implementation of the work programme; and
- decides to provide further guidance to the GEF for capacity building, facilitating access to proprietary technologies, and providing incentives for technology diffusion.

The draft work programme contains four programme elements, which include objectives, operational targets, activities, main actors and timelines.

Programme Element 1 on technology assessments establishes targets on: national technology needs assessments; impacts and risk assessments; and dissemination of information and methodologies for assessments through the CHM.

Element 2 on information systems sets targets on: the development of the CHM as a central mechanism for information exchange and facilitating technology transfer and cooperation; national information systems and their linkages to international information systems; and further cooperation in the development of information systems.

Element 3 on enabling environments contains targets on: facilitation of access to, and transfer of, relevant technologies; and national frameworks to facilitate cooperation and access to, and adaptation and absorption of, relevant technologies.

Element 4 on capacity building and enhancement includes operational targets addressing capacity building for national technology assessments, information systems, national policy reviews and enabling environments.

CBD work programme and the millennium development goals

Final Decision: In the decision (UNEP/CBD/COP/7/L.9), the COP urges the implementation of development activities in ways that are consistent with, and do not compromise, the achievement of the objectives of the CBD and the 2010 target. The COP invites integration of the MDGs into the Convention's work programmes, and requests the Executive Secretary to bring forward options for consideration at COP-8 for a cross-cutting initiative on biodiversity for food and nutrition.

Multi-year programme of work

Final Decision: In the decision (UNEP/CBD/COP/7/L.7), the COP decides to:

- adopt the annexed MYPOW and the ToR for the AHTEG on Island Biodiversity;
- consider items identified as priorities by the WSSD when undertaking in-depth reviews of existing thematic areas and cross-cutting issues;
- identify, for each upcoming meeting, ways to address issues of overarching importance, particularly relevant socio-economic issues identified by the WSSD;
- assess progress in achieving the goals of the Convention's Strategic Plan, 2010 target and relevant MDGs at each of its meetings until 2010; and
- consider a maximum of six items for in-depth review at any COP.

The COP requests the Executive Secretary to develop a preparatory process for SBSTTA's work on island biodiversity, which includes electronic forums, an AHTEG and a liaison group, and allows for the widest possible input.

The annexed MYPOW identifies island biodiversity as the new issue for in-depth consideration, issues for in-depth review, and strategic issues for evaluating progress in implementation for COP-8, COP-9 and COP-10. The annexed ToR for the AHTEG on Island Biodiversity contain a mandate to, *inter alia*:

- review the status of, and major threats to, island biodiversity;
- review how ongoing work under the Convention and other processes

is contributing to the implementation of the Convention's objectives regarding island ecosystems;

- identify significant gaps and constraints;
- develop proposals for a work programme; and
- develop global outcome-oriented targets pertaining to priority actions.

Operations of the convention

Review and consolidation of COP decisions

Final Decision: In the decision (UNEP/CBD/COP/7/L.21), the COP retires COP-3 and COP-4 decisions listed in an annex, and adopts a phased process of consolidation of COP decisions to be undertaken under the guidance of the Bureau. The COP invites the UNEP Executive Director and the CBD Executive Secretary to review and revise the administrative arrangements between UNEP and the CBD Secretariat and report thereon to COP-8.

Rule 21

Final Decision: In the decision (UNEP/CBD/COP/7/L.21/Add.1), the COP notes that there has not been enough experience with the operation of the new arrangements, and decides to review at COP-8 the effectiveness of the changes to Rule 21, and Rule 4 of the Rules of Procedure relating to the periodicity of its ordinary meetings. The COP requests the Executive Secretary to seek the views of Parties on options for a mechanism for setting priorities during the COP.

Access and benefit-sharing

Final Decision: The decision (UNEP/CBD/COP/7/L.28) provides for the following:

- Bonn Guidelines on ABS: The COP calls for promoting their implementation and encourages submission of information on experience and lessons learned.
- Use of terms: The COP requests submission to the ABS Working Group of a compilation of information
- Definitions of: access to genetic resources; benefit-sharing; commercialization; derivatives; provider; user; stakeholder; *ex-situ* collection; and voluntary nature.

- Other approaches: The COP requests a report on the basis of submissions on other approaches to complement the Bonn Guidelines, for consideration by the ABS Working Group.
- International ABS regime: The COP decides to mandate the ABS Working Group, with the collaboration of the Working Group on Article 8(j), to elaborate and negotiate an international ABS regime, with the aim of adopting an instrument/instruments. It calls for the necessary arrangements for the ABS Working Group to convene twice before COP-8.

It further: invites the cooperation of FAO, WTO, WIPO, and the International Union for the Protection of New Varieties of Plants (UPOV); encourages community participation; and requests the Executive Secretary to compile submissions on the regime's elements.

The annexed ToR for the ABS Working Group to negotiate an ABS regime includes terms on process; nature; scope, and elements. The ABS Working Group is called upon to: elaborate and negotiate the nature, scope and elements of an international ABS regime, drawing on, *inter alia,* an analysis of existing instruments; and examine whether the identified elements are part of these instruments, and address the gaps.

It is noted that the international regime could be composed of one or more instruments within a set of principles, norms, rules and decision-making procedures, legally-binding and/or non-binding. The regime's scope covers access to genetic resources and promotion and safeguarding of benefit-sharing and traditional knowledge, innovations and practices in accordance with Article 8(j).

A list of elements to be considered by the ABS Working Group includes, *inter alia*:

- measures ensuring: collaborative scientific research and sharing of its results; sharing of benefits arising from the utilization of genetic resources and their derivatives and products; compliance with national legislations on ABS, PIC and MAT; and compliance with PIC of

indigenous and local communities holding associated traditional knowledge;
- measures preventing unauthorized access to genetic resources;
- the issue of derivatives;
- certificates of origin/source/legal provenance;
- disclosure requirements in IPR applications;
- protection of community rights over their traditional knowledge and customary law;
- instruments to ensure benefit-sharing with communities;
- monitoring, compliance and enforcement;
- dispute settlement and/or arbitration; and
- relevant elements of existing instruments and processes.

Regarding measures to support compliance with PIC and MAT, the COP, *inter alia*, invites Parties to: establish national mechanisms to ensure compliance, when required by domestic law, with the obtaining of communities' PIC; and establish mechanisms to ensure benefit-sharing at the national level with relevant stakeholders and indigenous and local communities. The COP also requests the ABS Working Group to address issues related to an international certificate of origin/source/legal origin, and to identify issues related to disclosure requirements in IPR applications. The COP invites WIPO to examine issues regarding the interrelation of access to genetic resources and disclosure requirements in IPR applications, and requests the Executive Secretary to gather information on compliance-related issues and make the compilation available for the ABS Working Group's consideration.

Regarding capacity-building needs, the COP adopts the Action Plan on capacity building for ABS. The annexed Action Plan includes sections on: its objective; key areas requiring capacity building; mechanisms for implementation of capacity building; coordination; and an appendix on possible approaches for implementing identified activities.

Article 8(j)

Final Decision: In the decision (UNEP/CBD/COP/7/L.19/ Rev.1), the COP decides to hold one intersessional meeting of the Article 8(j) Working Group, and requests the Executive Secretary to prepare a progress report on the integration of Article 8(j) into thematic areas.

Regarding GURTs, the COP: invites Parties to build capacity to enable farmers and indigenous communities to effectively participate in decision-making processes related to GURTs; invites comments on the recommendation of the AHTEG on GURTs, and urges the Article 8(j) Working Group to consider the potential adverse socioeconomic impacts of GURTs on communities at its next meeting.

Regarding phase one of the composite report on the status and trends of traditional knowledge, the COP urges Parties and communities to provide information through the CHM, and requests the Executive Secretary to continue work through regional workshops and additional information gathering.

Regarding phase two of the composite report, the COP encourages Parties to support community field studies to determine threats to traditional knowledge. It further calls for financial support for work on both phases and for the development of an action plan. The annexed draft elements of an action plan for the retention of traditional knowledge include: an improved monitoring and reporting process; indicators; research ethics; and capacity building, education and training.

On the Akwé: Kon Guidelines, annexed to the decision, the COP encourages: legal and institutional reviews of impact assessments; Parties to involve indigenous and local communities in impact assessments, take steps to ensure transparency, and provide the necessary capacity and funding to ensure that the measures are implemented; and communities to request application of the Guidelines when developments are proposed in their traditional territories.

Regarding participatory mechanisms, the COP reiterates its invitation to increase indigenous participation on delegations, and requests the Executive Secretary to compile information on indigenous participation in the CBD and implementation at the national level, and to incorporate practical measures to enhance indigenous participation at SBSTTA and COP meetings. It decides to establish a voluntary funding mechanism under the CBD to facilitate indigenous participation, giving special priority to participation from developing countries, countries with economies in transition and SIDS. The COP also requests the Executive Secretary to further develop the role of the thematic focal point in the CHM, and to assist in developing communication networks for communities.

Regarding the development of elements of *sui generis* systems for the protection of traditional knowledge, the COP requests the Executive Secretary to compile information on customary laws and to develop a glossary of terms relevant to Article 8(j). It further decides on mechanisms for better cooperation between the ABS and Article 8(j) Working Groups. It requests the Article 8(j) Working Group, in collaboration with relevant international organizations, to:

- consider forms of, and develop as a priority issue, elements for *sui generis* systems for the protection of traditional knowledge;
- review the relevance and applicability of the Bonn Guidelines to the Article 8(j) Working Group;
- assess the role of databases and registers; and
- explore the conditions under which the use of existing IPRs can contribute to reaching the objectives of Article 8(j).

An annex contains potential draft elements to be considered in the development of a *sui generis* system for the protection of traditional knowledge.

Regarding recommendations of the UN Permanent Forum on Indigenous Issues (PFII) to the CBD, the COP requests the Executive Secretary to contribute to the preparation of a report on the implementation of Chapter 26 (indigenous peoples) of Agenda 21, and transmit the Akwé: Kon Guidelines to the third session of the PFII.

The COP requests the Article 8(j) Working Group to develop draft elements of an ethical code of conduct to ensure respect for the cultural heritage of indigenous and local communities for biodiversity conservation and sustainable use.

Scientific and technical cooperation and the CHM

Final Decision: The decision (UNEP/CBD/COP/7/L.6) includes sections on the CHM and operational procedures for the CHM's informal advisory committee.

The COP decides to extend the mandate of the CHM's informal advisory committee and review its mandate at COP-9. The COP calls upon Parties to: use the CHM toolkit to establish national focal points and websites; contribute resources for translation; and use controlled CBD vocabulary to facilitate inter-operability among national CHMs. It invites developed country Parties to develop regional CHMs, and to assist developing country Parties.

The COP requests the Executive Secretary to, *inter alia*: use the CHM to strengthen collaboration with international partners and organizations; update the CHM's strategic plan; convene regional workshops; update the CHM toolkit; and develop a web portal on island biodiversity. It also calls on the CHM's informal advisory committee to assess the results of the independent review of the CHM, and assist the Executive Secretary to strengthen the CHM's role in promoting technical and scientific cooperation.

The COP decides to adopt the annexed operational procedures for the CHM's informal advisory committee. The operational procedures include sections on: objectives, operational procedures, membership, Chair, and meetings.

Communication, education and public awareness

Final Decision: In the decision (UNEP/CBD/COP/7/L.22), the COP invites Parties to take into consideration the need to communicate the 2010 target and to establish appropriate linkages to the Decade on Education for Sustainable Development in the implementation of national CEPA programmes.

It further requests the Executive Secretary to:

- allocate a specific CEPA post in the Secretariat;
- convene an informal advisory committee on CEPA at the next SBSTTA meeting to further develop the CEPA work programme; and
- continue collaborative efforts with CEPA programmes of other relevant organizations, including the Rio Conventions.

The COP also invites financial support for the implementation of the CEPA work programme and national CEPA programmes, and requests Parties to contribute to the second edition of the Global Biodiversity Outlook.

Financial resources and mechanism

Final Decision on additional financial resources: In the first decision (UNEP/CBD/COP/7/L.24), the COP welcomes the replenishment of the GEF, and urges Parties to: take action to ensure effective implementation of the work programmes, the Strategic Plan, and associated targets; and implement the Monterrey Consensus on Financing for Development. The COP encourages Parties to further explore opportunities to utilize debt relief instruments, and invites them to enhance the integration of biodiversity into their sectoral development and assistance programmes. The COP requests the Executive Secretary to continue compiling and disseminating biodiversity-related funding information.

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Final Decision on arrangements for the third review of the effectiveness of the financial mechanism: In the decision (UNEP/CBD/COP/7/L.25), the COP adopts the annexed guidelines for the third review of the effectiveness of the GEF, containing the objectives, methodology, criteria and procedures of the review, which is to be conducted prior to COP-8 by an independent evaluator and under the authority of the COP. It further decides to take appropriate action to improve the effectiveness of the mechanism, if necessary, on the basis of the review.

Final Decision on further guidance to the GEF: In the decision (UNEP/CBD/COP/7/L.26), the COP decides that the GEF shall provide financial resources to developing country Parties for country-driven activities and programmes, consistent with national priorities and objectives, and taking fully into consideration all relevant decisions from the Conference of the Parties. The decision further contains specific guidance related to COP-7 decisions.

National reporting

Final Decision: In the decision (UNEP/CBD/COP/7/L.8), the COP requests Parties to facilitate the preparation of the third national report and, along with donors, to strengthen Parties' capacities in implementing the Convention. The COP further requests the GEF to expedite and simplify its procedures for allocating funds to prepare national reports. The COP also requests Parties to submit as much information as available for evaluating the CBD's implementation and progress towards the 2010 target

Liability and redress

Final Decision: In the decision (UNEP/CBD/COP/7/L.5), the COP: renews its request to the Executive Secretary to convene a group of legal and technical experts on liability and redress; and urges Parties to make the necessary voluntary financial contributions.

Incentive measures

Final Decision: In the decision (UNEP/CBD/COP/7/L.33), the COP encourages Parties to use the annexed draft proposals as voluntary interim guidance for ways to mitigate perverse incentives, and requests SBSTTA-10 to further refine them.

Regarding implementation of the work programme on incentive measures, the COP invites Parties and international organizations to submit case studies on non-monetary positive incentives for the conservation and sustainable use of biodiversity. The COP requests the Executive Secretary to: prepare a synthesis report and an analysis of instruments that provide positive incentives, for consideration by SBSTTA prior to COP-8; and explore existing methodologies for the valuation of biodiversity by preparing a compilation of existing valuation tools. The annexed draft proposals for ways to mitigate perverse incentives remain in brackets. The proposals contain sections on: general considerations, identification of policies or practices that generate perverse incentives; design and implementation of appropriate reforms; and monitoring, enforcement and evaluation of reforms.

Cooperation with other conventions

Final Decision: In the decision (UNEP/CBD/COP/7/L.23), the COP recognizes the leading role of UNEP in environmental issues, the role of the Joint Liaison Group for coordination between the Rio Conventions and the CPF in forestry issues. It urges enhanced cooperation and reduction of inefficiencies between the CBD and all relevant international conventions. It requests the Executive Secretary to invite the Secretariats of the biodiversity-related conventions to form a liaison group to enhance coherence, examine options for a flexible framework between all relevant actors, such as a global partnership on biodiversity, and report to COP-8 on possible ways forward. It further requests the Executive Secretary to renew his application for observer status in relevant WTO bodies, and to inform the Working Group on the Review of the Implementation of the Convention on ongoing work on cooperation.

***Source:** Earth Negotiation Bulletin.*

Seventh Latin American Meeting in Hematology, Immunology and Transfusion Medicine

Hematology Hababana'2005 has organized a meeting in Hematology, Immunology and Transfusion Medicine on May 16-20, 2005 at International Conference Center, La Habana, Cuba. The Seventh Latin American Conference is organized in collaboration with Fifth National Congress. For more information contact Prof. Josè M. Ballester, President, Hematology Habana' 2005, Tel: (537) 578268, 578695, 2085199, Fax: (537) 442334, 202-8382, Email: ihidir@hemato.sld.cu, aliciag@palco.cu, Website: www.loseventos.cu/hemalogia2005.

World Congress on Industrial Biotechnology and Bioprocessing

The first World Congress on Industrial Biotechnology and Bioprocessing will be held on April 21 to 23, 2004 at the Walt Disney World Swan and Dolphin Hotel in Orlando, Florida. Jointly hosted by the Biotechnology Industry Organization (BIO), the American Chemical Society, and the National Agriculture Biotechnology Council, the congress focuses on how industrial biotechnology is currently used to transform manufacturing, chemical synthesis, and energy production. The conversion of agricultural wastes, such as corn stalks and rice, into new consumer goods will also be highlighted. More information about the World Congress can be seen at http://www.bio.org/worldcongress.

Summary Report on the Global Status of GM Crops in 2003

The Global Knowledge Center on Crop Biotechnology (KC) has recently released the summary report on the current global status of GM crops. This latest data is downloadable at http://www.isaaa.org/kc.

Asian Bio-Net

The Coordinator of the Food and Agriculture Organization (FAO) BiotechNet News announced the launch of Asian Bio-Net, the website of the FAO project on Capacity Building in Biosafety of GM Crops in Asia, based at the FAO Regional Office for Asia and the Pacific. The project, supported by the Government of Japan, was formulated to "assist countries in the region in safe harnessing of the benefits of biotechnology in accordance with relevant global agreements on the subject." Please visit http://asiabionet.org for details.

New K-Sheet

The National Center for Food and Agricultural Policy's (NCFAP) December 2003 study entitled "Plant Biotechnology: Potential Impact for Improving Pest Management in European Agriculture," is the latest Knowledge (K) Sheet from the Global Knowledge Center on Crop Biotechnology of the International Service for the Acquisition of Agri-biotech Applications (ISAAA-KC). Authored by Leonard Gianessi, Sujatha Sankula, and Nathan Reigner, this comprehensive report examines nine case studies on the potential impacts of biotech crops on European agriculture. Download the K-Sheet at http://www.isaaa.org/kc.

International Year of Rice Celebration in Africa

International Year of Rice (IYR) events have been planned across. The 23rd Session of FAO African Regional Conference would be from March 1-5, 2004 at Johannesburg, South Africa. The International Year of Rice promotes improved production and access to this vital food crop, which feeds more than half the world's population while providing income for millions of rice producers, processors and traders. For more information visit http://www.fao.org/rice2004/en/calendar.htm

ASFARNET Newsletter

The Asian Farmers Regional Network (ASFARNET) released a newsletter highlighting its first meeting which was held in Thailand earlier this month. ASFARNET was organized during a capacity building workshop held in Manila and Cagayan de Oro City, Philippines last December 2003. For the full newsletter article and more information about ASFARNET, visit http://www.searca.org/~bic/resources/newsletters/ASFAR-Feb2004.pdf

Paper on Wheat Imporvement

A summary of David Hoisington and colleagues' paper entitled "The application of biotechnology to wheat improvement" is posted in the document cabinet of the Global Knowledge Center on Crop Biotechnology together with other recent papers. Hoisington, who is affiliated with the International Maize and Wheat Improvement Center (CIMMYT), together with his colleagues, analyzed how biotechnology can improve the wheat crop. View the summary and other articles at http://www.isaaa.org/kc.

Biotechnology enterprise in Germany*

Biotechnology is identified as a key technology for the German Government at different levels. The general policy goals are to promote basic research as well as high level research to support research efforts in the environment, health, nutrition, energy and raw materials supplies to improve the research infrastructure (particularly the framework conditions for research and development in industry); to foster investigations on safety and ethical issues and to strengthen technology transfer and commercialisation, e.g. by supporting SMEs.

The "Biotechnology 2000" covered the period from 1990 to 2000. The aim of the programme was to strengthen the process from invention to innovation and to extend the scientific base. The programme activities centred on the human health and environment areas.

The Faktenbericht forschung 2002 report indicates that EUR 179 million will be spent on the National Genome Research Network from 2001-2003. The National Genome Research Network will fund research in five areas of disease and disorders that affect large numbers of people. As well as funding human health research the National Genome Research Network will integrate ethical, social and legal issues of genome research.

The Federal Government also allocated in both 2001 and 2002 approximately EUR 150 million to "Biotechnology - using and shaping the opportunities". This programme supports innovation in biotechnology and genetic engineering as well as funding genome research and supporting reorganisation on industrial processes with the help of biotechnological methods to make them more sustainable (Federal Ministry of Education and Research).

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* Based on OECD (2003). "Biotechnology Statistics Predominantly from Official Sources" Working Party of NESTI.

The European Biotechnology Innovation Systems (EBIS) report that the German public's general perception of biotechnology is sceptical, especially with respect to genetic engineering approaches in agriculture and food processing. The German Government has sought to address some of these fears through public education, of which an example includes a programme to enable school pupils to consciously cope with new technologies in general and with modem biotechnology in particular.

In 2001 the German Federal Office conducted a voluntary survey of biotechnology enterprises. The Federal Statistical Office estimates that the definition used in their survey aligns itself to the narrower OECD definition.

Based on survey responses from 876 enterprises, the Federal Statistical Office estimates that there are 18 839 people employed in biotechnology. Furthermore 9 906 people were employed in 'core biotechnology enterptlses', of which the majority of enterprises had 100 or more employees.

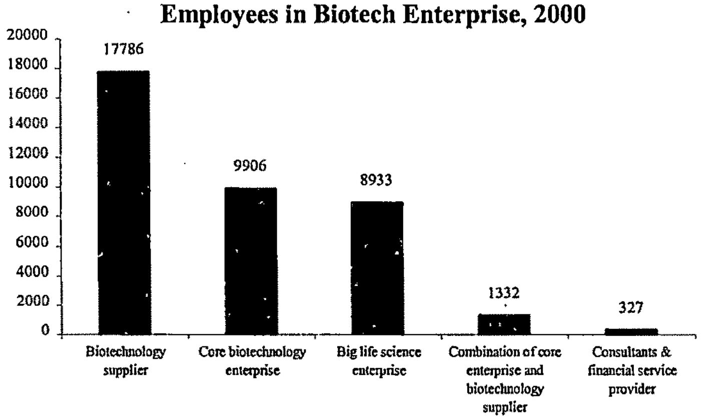
The German Federal Statistical Office estimates that there are between 500 and 550 core biotechnology enterprises that work with mainly modem biotechnological procedures. The core biotech enterprises which provided information in the survey reported turnover per employee of just under EUR 60,000. However it is especially the larger businesses of the list sciences industry that contribute much to - the economic power of biotechnology ip. Germany. The 24 big enterprises in life science who responded reported a turnover (biotechnological products) per employee of just under EUR 388 000.

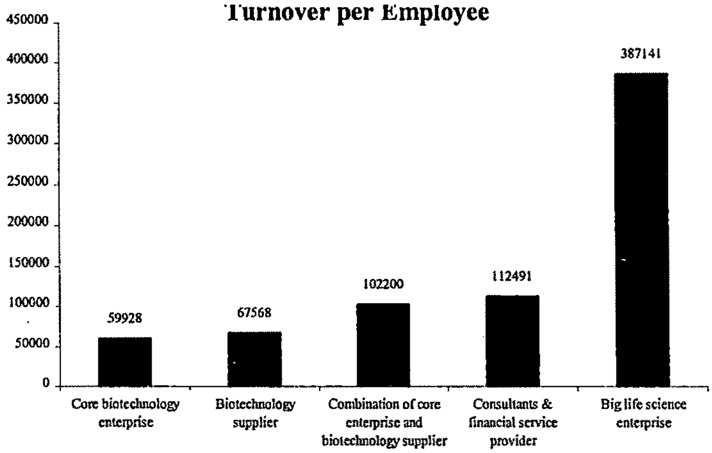
Large enterprises in life science industry reported a total turnover over of about EUR 3.5 billion in 2000. Core biotech enterprises reported a total turnover of EUR 594.

EUROSTAT's NCRONOS database which reports on Government budgetary allocations or outlays to R&D recorded German biotechnology

GBAORD as being EUR 501.625. This figure reflects all public expenses associated with biotechnology.

The official report "Faktenbericht Forschung 2002" of the Federal Ministry of Education and Research (BMBF) reported that the German Federal Government had allocated EUR 261.3 million to biotechnology research funding for 2000. This compares with EUR 246 million for each of 1998 and 1999 and EUR 324 million for 2001.





Sources: European Biotechnology Innovation Systems (EBIS), Case Studies Germany Wörner *et al.* July 2000. EUROSTAT, NCRONOS database and Faktenbericht Forschung, 2002, Federal Ministry of Education and Research (BMBF).

Printed and published by Dr. Nagesh Kumar, Director-General, on behalf of Research and Information System for the Non-Aligned and other Developing Countries (RIS), and printed at Multiplexus (India), 94, B.D. Estate, Timarpur, Delhi-110 054. Ph. 23818103 and published at Zone IV-B, Fourth Floor, India Habitat Centre, Lodi Road, New Delhi-110003.

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ASIAN IOTECHNOLOGY AND DEVELOPMENT REVIEW

Gift 5/11/04

Vol. 6 No. 3 July 2004

- Asian Regional Cooperation in Biotechnology
- Biotechnology and International Trade Regime: Options before Developing Countries
  Sachin Chaturvedi and S. R. Rao
- Domestic Import Regulations for Genetically Modified Organisms and Their Compatibility with WTO Rules
  Heike Baumüller
- Policy and Development of Biotechnology: Bangladesh Perspective
  N. Choudhury

Recommendations of the Second Conference on Biotechnology for Asian Development

RIS

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RNI Registration No. DELENG/2002/8824
ISSN: 0972-7566

Printed by: Multiplexus (India) 94, B.D. Estate, Timarpur, New Delhi (India) Ph. 2778 2485/86.

The views expressed in the *Asian Biotechnology and Development Review* are those of the authors and not necessarily those of the RIS or the organisations they belong to.

This journal is abstracted in ***Cab International*** and ***Science of Science***, of Council for Scientific and Industrial Research (CSIR), New Delhi.

ASIAN
BIOTECHNOLOGY AND DEVELOPMENT
REVIEW

ASIAN BIOTECHNOLOGY AND DEVELOPMENT REVIEW

Vol. 6 No. 3 July 2004

Contents

Harnessing Biotechnology for Development 1
K. C. Pant

Asia and Bioeconomy: Growing Synergies 5
M. Tawfik

Biotechnology and International Trade Regime: 9
Options before Developing Countries
Sachin Chaturvedi and S. R. Rao

Domestic Import Regulations for Genetically Modified 33
Organisms and Their Compatibility with WTO Rules
Heike Baumüller

Policy and Development of Biotechnology: Bangladesh Perspective 43
N. Choudhury

Recommendations of the Second Conference on 75
Biotechnology for Asian Development

Bio News 79

Document
- Kuala Lumpur Declaration on Biological Diversity 95
- Note on Liability and Redress 97

Bio Web 101

Bio Stats: Statistics on US Biotechnology 105

Harnessing Biotechnology for Development

K. C. Pant*

I am pleased to inaugurate the Second Conference on Biotechnology for Asian Development being organized by RIS in collaboration with CII and IUCN, and with the support of UNESCO and DBT. I recall being at the First Asian Conference organized here by RIS two years ago and I am happy to note that the policy dialogue initiated at that conference for harnessing the potential of this new core technology for Asian development is continuing. I am particularly pleased to see scholars and experts here from many Asian countries besides experts from international development institutions.

For some time now there has been a discussion on the potential of biotechnology for development. It is now well established that these technologies provide valuable tools for meeting a number of developmental challenges in different areas. In agriculture for instance, the high yielding varieties which have been extensively used since the mid-sixties and ushered in green revolution are not only reaching a plateau in terms of yields but are not sustainable given their heavy dependence on chemical fertilizers, pesticides and irrigation. Biotechnology provides tools for addressing the yield growth in a more sustainable manner by developing low cost varieties based on use of biofertilizers and integrated pest management and hence are more appropriate for small and marginal farmers in developing countries. Biotechnological tools can also be used to improve the nutritional content of food crops so as to address the problem of malnutrition in developing countries.

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Inaugural Address at Second Conference on Biotechnology for Asian Development: Regional Cooperation for Ensuring Access and Capacity Building, New Delhi, April 7-8, 2004.

Biotechnologies are revolutionizing the health care system with new diagnostic tools, medicines and drug delivery systems. Recent developments in genome research have the potential of transforming the healthcare system beyond recognition. Biotechnologies also find major applications for development of environmentally friendly technologies in industry, in non-conventional energy, mining, food processing, among many others.

Recognizing the potential of these technologies, the governments worldwide have taken steps to harness them for their development. Several Asian countries have built impressive institutional infrastructure and capability in different areas of applications. These countries can fruitfully cooperate in various ways to exploit their synergies and expertise in the sphere of biotechnology for mutual benefit. Some initiatives at regional cooperation are already on in the framework of Asian Cooperation Dialogue (ACD), in ASEAN-India context, and in SAARC, among others. I am happy to note that the focus of the Conference this time is on regional cooperation for ensuring access and capacity building. I believe that regional cooperation in this area can usefully complement the growing Asian regional economic integration in trade and investment among other areas. Regional cooperation can also be fruitful in building a more development friendly international regime for harnessing the potential of these technologies.

An important issue in context of WTO concerns the import regulations for genetically modified food and other items. At present there are very few countries where production and import of GM crops are completely legalized. Various WTO committees like the Committees for Sanitary and Phyto-Sanitary (SPS) Measures and Technical Barrier to Trade (TBT) are discussing issues like traceability and labelling, equivalence and precautionary principle, etc. I believe that a collective thinking and coordination by Asian countries at these Committees and other forums would be fruitful.

Furthermore, as we look forward in context of diffusion of GM crops across developing countries, we realize that a key focus has to be on capacity building in terms of handling GM crops in the fields. One needs to take lessons from the experiences with Bt Cotton and Corn in a number of countries with respect to issues relating to labelling, traceability and biosafety management. Sharing of these experiences can be fruitful. The regulatory issues concerning biosafety are being discussed at international level. The Seventh Conference of Parties (COP) held at Kuala Lumpur in February this year has advanced the agenda for meeting the objectives of the Convention of Biological Diversity (CBD) and the Cartagena Biosafety Protocol.

Apart from building a consensus on biosafety issues there are two more important issues which I believe need to be considered. One is to explore the possibility of launching genetic literacy drive to ensure wider popular participation in the biotechnology revolution.

The second is to see that investment in R&D and production by both public and private sectors is channelled in areas of highest social priority rather than driven by purely commercial considerations. This is important if we are to fully harness the potential of these powerful technological tools. This in turn requires an enabling environment for growth of biotechnology industry in terms of intellectual property rights (IPRs) regime, availability of institutional infrastructure, finance and venture capital, etc. One of the areas of concern in this respect is the tightening regime of intellectual property protection. In particular, the patent protection on research tools necessary for further development such as expressed sequence tags (ESTs) and restriction enzymes, etc. can adversely affect accessibility of these technologies by developing countries. In the earlier technology revolutions such generic tools used to be in public domain available to researchers everywhere. We need to debate the implications of such trends and draw the attention of the international community to respond to them.

I hope that biotechnology industry can further speed up the growth in Asia especially with regional cooperation. Asia is a continent known for rapid economic progress over the past fifty years. The Japanese example of rapid growth in the 1960s and 1970s was followed in rapid succession by several other Asian countries such as South Korea, Singapore, Taiwan, Malaysia, Thailand and Indonesia and 7 per cent annual growth became a routine affair in east Asia. China has achieved an average growth rate of about 9 per cent per year since 1980. Once considered as a laggard, South Asia has grown at about 5.5 per cent on average over the past two decades and the current growth outlook is much brighter. The Indian economy is currently growing at about 8 per cent per annum. With the rise of China and India, it is now clear that the center of gravity of the world economy will shift to Asia in the 21st century. A recent study by Goldman Sachs shows that China and India would emerge among the top three economies of the world in the next 50 years.

I am sure that this Conference will address these and many other challenges that the policy makers face in the Asian countries. I hope that you will come out with useful findings and policy lessons for capacity building in this important area of technology including those pertaining to regional cooperation in Asia.

Asia and Bioeconomy: Growing Synergies

M. Tawfik*

I am glad to address this august gathering on UNESCO's involvement in Life Sciences Programme.

In the life sciences, UNESCO's efforts will focus on the development of institutional capacity and infrastructure by providing catalytic support to international centres, national institutions and UNESCO Chairs in the life sciences and biotechnologies.

UNESCO will continue its efforts in strengthening human capacities, with special emphasis on capacities for scientific research in molecular and cell biology and biotechnology, highlighting food security, poverty alleviation and awareness building in bio-safety issues, both within the research community and in the public domain. This will be achieved through support for specialized and high-level conferences like this event.

Strengthening of networking programmes (e.g. in collaboration with the Global Network of Molecular and Cell Biology (MCBN) and MIRCENs) at national, regional and international levels, as well as the development of new interdisciplinary projects will be used to foster capacity-building and sustainable development. UNESCO will contribute to the development and use of technology-enhanced information dissemination tools to improve scientific information dissemination and understanding of advances in life sciences,with a concomitant emphasis on further development and use of bioinformatics.

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* Director and UNESCO Representative, New Delhi.

Remarks at the Second Conference on Biotechnology for Asian Development "Regional Cooperation for Ensuring Access and Capacity Building in Asia", New Delhi, April 7-8, 2004.

Biotechnology is an integral part of the knowledge-based economy and thus an important means of wealth creation. It is ushering a new model of economic activity (bio-economy) whereby new types of enterprises are created and old industries are revitalized. Its potential to spur economic growth and enhance industrial productivity is unprecedented. Biotechnology offers developing countries significant opportunities to address critical social, economic as well as specific industrial development problems.

Biotechnology cannot only reduce disease and food insecurity in developing countries, but also power the creation of employment and wealth. Biotechnology has a huge potential to contribute to socio-economic development of developing countries and those with economies in transition. The global and ever increasing problems of water and food security, the toll of the HIV/AIDS pandemic, newly emerging and re-emerging diseases on fragile economies, hamper national development and threaten global peace initiatives in the developing and least developed countries especially those with an agrarian based economy.

UNESCO's programmes in the life sciences aim at promoting international scientific co-operation in these fields, and bridging the scientific and technological differences existing between developed and developing countries. The major focus is the development of endogenous national and regional research capacities in the biological sciences and biotechnologies, for especially the developing countries.

Recently concluded Global Biotechnology Forum during March 2004 at Chile urged research institutions and UN organizations to advance agricultural and other areas of research into new technologies, including biotechnology, and concluded that the introduction of such new tried and tested technologies should be accomplished in a safe manner, within appropriate regulatory frameworks, and adapted to local conditions to help improve agricultural productivity in developing countries.

The forum examined the role of biotechnology in the developing world and especially in meeting the needs of the poor and improving their quality of life, as well as its impacts on environment, trade, and public perception. A number of key issues affecting the development of biotechnology in the developing world were identified: inadequate scientific, technical and research capabilities, the absence of entrepreneurial skills and of public investment in this field, the presence of intellectual property barriers, different biosafety regulations and difficult market access.

The meeting opened a dialogue meant to develop proposals, initiatives and solutions for action, such as the establishment of a multi-stakeholder forum for informed dialogue on biotechnology and its benefits for the developing world, the creation of a network and database on biotechnology activities in developing countries and those with economies in transition, including global market and technology information for partnership facilitation, enhancement of capacity-building activities, and the assessment of intellectual property legislation on biotechnology.

The participants of the forum also emphasized creation of an information network and data base as to what biotechnology activities are currently in progress in the countries with economies in transition and developing countries, together with market information on a global basis to assess technology and market potentials for new initiatives, including to identify and facilitate partnerships. The present conference is being organized by RIS and IUCN with supports from UNESCO and Department of Biotechnology, Government of India as a stepping-stone to begin this exercise in this part of the world.

I would like to mention to this gathering that UNESCO is just started International Basic Sciences Programme (IBSP) a new inter-governmental initiative under basic sciences to examine and facilitate the national/Regional/ International collaboration in Basic Sciences. Also we are in the process of negotiation with Government of India in developing a dedicated regional centre for education and training in Biotechnology under Department of Biotechnology.

Biotechnology and International Trade Regime: Options before Developing Countries

Sachin Chaturvedi[*]
S. R. Rao[**]

In recent past, adoption and diffusion of biotechnology has raised several policy challenges for the governance of this technology especially in the developing countries due to rapid expansion of the biotechnology industry. These countries have been strategically strengthening capacity, infrastructure and expertise in regulation and commercialization of biotechnology particularly in the areas where rich bioresources are utilized. The applications of this technology, both in pharmaceuticals and agriculture, are finding new vistas of economic growth for developing countries. Illegal introduction of GM products, threat of overexploitation of natural resources (their biomolecules and genes), potential risks to environment and global contention on the technology has confounded the prevailing confusion on some of the intricate issues linked to the trade and biosafety of GMOs. However, the position taken by the civil society organizations and some of the national governments especially from Europe and Africa have highlighted the growing polarization on this issue. These discussions have important implications not only for developed countries which are major exporters of GM goods but also for some of the developing countries which have infused

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GM goods in the production chain. Developing countries, that are major exporters of non-GM agricultural goods, are also affected due to requirement of GM free certification by some importers. This affects the exports of developing countries adversely.

The related challenge is that the international regulatory arrangements like the Cartagena Protocol on biosafety have yet to become effective international instruments to guide policy frameworks dealing with transboundary movement of GMOs. The development of multilateral, regional and national standards and regulations for the release, safety assessment of food from genetically modified organisms has to be formulated as per the letter and spirit of the Convention on Biological Diversity (CBD). Along with this, the negotiations are taking place in other international organisations such as the WTO, which may have impact on international trade. They include Technical Barriers to Trade (TBT), the Sanitary and Phytosanitary Measures (SPS), Trade-related Aspects of Intellectual Property Rights (TRIPs) and Agreement on Agriculture. They also become relevant in the overarching trade issues such as market access and competitiveness.

This paper makes an effort to critically analyze each of these dimensions of international negotiations and emerging perspectives for developing countries. Section II takes an account of the global status of biotechnology while Section III discusses at length the Cartagena Protocol and different national regulatory regimes. In Section IV, WTO and trade related implications are analyzed.

Adoption and Diffusion of Agricultural Biotechnology

In the last one decade or so, the area under commercial cultivation of GM crops has gone up many times. Between 1996 and 2001, the area under transgenic crops in industrial countries increased (5.6 million hectares) compared with developing countries (2.8 million hectares). The percentage growth was higher in the developing countries of the South (26 per cent) than in the industrial countries of the North (17 per cent).[1] The area under GMOs in the developing countries grew at a rate of 14 per cent in 1997 to

16 per cent, in 1998, to 18 per cent by 1999, 24 per cent in 2000 and 26 per cent in 2001. Thus, in 2001 it showed a rise of more than a quarter. Developing countries have almost 19 million hectares under transgenic crop cultivation. Latin American and CIS countries are the leading developing countries which have embarked on the GM adoption path in the last two years. However, no agricultural biotechnology product has yet been approved in the EU. In addition, several countries including Japan, Korea and temporarily Sri Lanka have already passed or are considering regulations mandating labelling for foods obtained from biotechnology.

In the US, in the year 2001, biotechnology varieties accounted for about 26 per cent of corn, 68 per cent of soybeans and 69 per cent of cotton planted.[2] These crops are the source of various ingredients used extensively in many processed foods, such as corn syrup, soybean oil and cottonseed oil. In Argentina, the main biotechnology crop is soybean while in Canada it is canola. As is clear, the total area under GM crops is 19 per cent of the total cultivated area while 46 per cent of the area under soybean is with GM crops and 7, 20 and 11 per cent under maize, cotton and grape, respectively. Thus, in some areas, concomitant cultivation of GM and non-GM leads to mixed produce. The extant of GM in non-GM produce has become a matter of concern for trade, both for raw and processed produce.

The global market of biotechnology has also grown rapidly in the last few years. In 1995 it was at $75 million while in 1998 it was $1.5 billion. This is now being projected to $6 billion by 2005. This period has also seen a very rapid rise in acquisition, alliances and mergers. There are several factors responsible for these initiatives. James (1998) explains that firms having larger status in pharmaceuticals/biotechnology are now entering in agricultural sector. In the period 1995-98 there were 25 major acquisitions and alliances, which alone were worth $17 billion. Out of them three major mergers were worth $13 billion. In this game of mergers Monsanto has emerged as the biggest player. It has acquired some of the largest firms in this US commodity markets and has got acquisition of important patents. For instance, DeKalb has 11 per cent of US commodity market with lots of important patents. Similarly, Delta & Pineland is the largest US company for cotton seeds. Monsanto has also acquired international seed operations of Cargill for $1.4 billion. Cargill specialised in seeds of corn, sunflower, rapessed, soyabean, alfalfa, sorghum, wheat and hybrid rice in 51 countries. Unilever owned Plant Breeding International Cambridge Ltd. (PBIC), earlier a public research institute has also been brought by Monsanto. PBIC largely focuses on cereal varieties and potato. Among the mergers, one finds creations of Novartis as a major step towards tapping of synergies in the biotechnology business. Ciba and Sandoz have merged their pesticide and seed business of $5 billion to take form of Novartis. Similarly, the impose of the merger of Hoechst and Rhone Poulenc to form Aventis was to achieve better operational efficiency. Aventis now has an R&D budget of $3 billion and annual sales of $20 billion, all over the world.

Advances in Biotechnology

These growth patterns are likely to go up as technology advances. Now biotechnology offers several ways by which average yield can be directly increased. One is through improvements in the "architecture" of the plant to enable it to absorb more photosynthetic energy or convert a larger portion of that energy into grain rather than stem or leaf. This was, in essence, the "Green Revolution" approach of breeding dwarfing genes into plants, so that the plants could make better use of fertiliser and water and produce more grain. This approach is being pursued in the new rice architecture being studied by the International Rice Research Institute (IRRI), Manila as well as by some private sector industry undertaking research in the fundamental mechanisms that controls plant architecture. Another approach for climates, where it is useful, to modify the plant for a shorter growing season by enhancing its efficiency in the use of fertilizer, pesticides and water. Molecular hybridization has also been demonstrated to increase the productivity of several crops, including rice and wheat, by 15 to 20 per cent.[3] It must be noted that the on-farm yield improvements observed so far have been for transgenic varieties developed to reduce on-farm production costs rather than for the purpose of increasing yields.

However, it is not yet clear whether yield-increasing experiences reflect a one-time advancement, or indicate achievement of a continuing increase in the yield. Considering that there are many new technologies that will, over time, be applicable for plant improvements and/or integrated into plants, the most reasonable conjecture is that the new technologies will continue to provide yield increases. These will be introduced on a regular basis, and that each of the associated yield increase will be somewhat more than historical trends.[4] Similarly, there are possibilities to improve the nutritional value of cereals by enhancing the presence of special nutrients or chemicals. A commercial example is the increase in the levels of biotin (vitamin H) for application in animal and human nutrition and development of golden rice with carotenoid production.

Public sector breeders have also been looking into similar special purpose applications, such as inserting genes so that vitamin A and iron becomes available through the consumption of rice.[5] Among the potentially more important applications for specific markets are those that seek to improve the quality of feed crops. New varieties of transgenic maize that contain higher oil levels to boost energy and improve feeding efficiency or have characteristics to reduce phosphorous in animal waste are examples that are currently under development.[6] In an interesting development that is certainly relevant to feed grains, is a patent covering the insertion of a protein into plants, which when eaten would facilitate control of animal parasites.

Developing crop varieties with many improved traits than single gene based single trait transgenics is also researched. Companies like Garst Seeds, a subsidiary of Advanta, has developed maize hybrids, which can tolerate two different classes of chemical herbicides.[7] In the United States, currently about 20 per cent of the maize production is destined for such markets, with the production of high-fructose corn syrup and of alcohol being the largest with a number of the industrial uses.[8] Maize and sorghum are among the crops that produce a high yield of starch/energy per hectare, and are the leading temperate zone crops for production characteristic of important crop plants within wide bounds, making it possible to use almost any starch producing plant for many industrial purposes.

There are also other non-traditional uses of cereal crops such as production cellulose, clearly available from other sources, but perhaps usefully produced in grain cultivation under certain circumstance. These developments may have significance for rice and other cereals, which are more widely grown in the developing countries. To the extent that imported cereals are priced higher than those domestically grown, using starch and other traits from domestically produced bio-engineered cereals in developing countries industries could lead to costs savings and boost farm incomes. Another important possibility is genetically altering crop plants for the production of proteins of pharmacological significance. Some of the patents in this area have wide applicability to different products, including for example, to the production of maize. One patent has very broad claims, but its example, emphasize production in rice. Several of the patents mention production of specific products not all of which are therapeutic. However, commercial applications of these technologies are not yet widely available. Cartagena Protocol and National Regulatory Regimes in Agricultural Biotechnology are two broad sets of regulatory regimes, which have become part of the system. One set emanates from national regulatory mechanisms evolved during last one decade and the other from the recently enforced Cartagena Protocol. The former, apart from having individual countries, also have groupings like the EU which has proposed to establish regulations requiring documentation to trace the presence of biotechnology products through each step of grain handling and food production processes. In fact, the EU now has also proposed to apply similar regulations for animal feeds.

It would be interesting to take stock of this important protocol. The Cartagena Protocol on Biosafety to the Convention on Biological Diversity was adopted by the Conference of the Parties to the Convention on 29 January 2000. In accordance with its Article 36, the Protocol was opened for signature at the United Nations Office at Nairobi by States and regional economic integration organizations from 15th to 26th May 2000, and remained open for signature at United Nations Headquarters in New York from June 5, 2000 to June 4, 2001. The Protocol has been signed on behalf of 107 States and regional economic integration organizations while very few have ratified. Ukraine is the 39th country to have ratified the Protocol in December 2002. The Protocol has become effective after the 50th ratification. India has also ratified this and the concerned Cabinet Committee has also cleared the proposal.

After five years of intense negotiations, governments have finalised this legally binding agreement for protecting the environment from risks posed by the transboundary transport of Living Modified Organisms (LMOs) using modern biotechnology.

This international protocol uses the term LMO rather than GMO. It is assumed that this is a more precise term. LMO is defined as, "Any living organism that possess a novel combination of genetic material obtained through the use of modern biotechnology" (Article 3 g). Under the Cartagena Protocol on Biosafety, governments will signal whether or not they are willing to accept imports of agricultural commodities that include LMOs by communicating their decision to the world community via an Internet-based Biosafety Clearing House. In addition, shipments of these commodities that may contain LMOs are to be clearly labelled. LMOs include various food crops that have been genetically modified for greater productivity or nutritional value, or for resistance to pests or diseases. Common examples include tomatoes, grains, cassava, corn, and soybeans. Seeds for growing crops are particularly important because they are used intentionally to propagate or reproduce LMOs in the environment. Together, these agricultural LMOs form the basis of a multibillion dollar global industry. Pharmaceuticals derived by using LMOs form the basis of an even larger industry (although pharmaceuticals are not covered by this agreement).

Stricter 'Advanced Informed Agreement' (AIA) procedures will apply to seeds, live fish, and other LMOs that are to be intentionally introduced into the environment (Article 7.2). In these cases, the exporter must provide detailed information to each importing country in advance of the first shipment, and the importer must then authorise the shipment. The aim is to ensure that recipient countries have both the opportunity and the capacity to assess risks involving the products of modern biotechnology. Moreover, the information should also include the modifications introduced; the technique used; the resulting characteristics of the LMO; the regulatory status of the LMO in the country of export and the contact details of the importer and the exporter. The notification has to be accompanied by a risk assessment report. Another important feature of the Protocol emanates from the Preamble as well as from the Articles 1, 10 and 11. This is "precautionary approach". This means that if there is a scientific uncertainty about the impact of genetic manipulation on biodiversity and human health, then the importer country may enforce restrictions on imports and this flexibility would remain till importer on its own arrives on scientific certainty about implications.

One of the most contentious issues that negotiators had to resolve involved the relationship between the Protocol and other international agreements, notably those under the WTO. It is important to ensure that the Protocol and the WTO are mutually supportive. The Protocol is not to affect the rights and obligations of governments under any existing international agreements. While at the same time one also has to ensure that the potentially dangerous activities can be restricted or prohibited even before they can be scientifically proven to cause serious damage.

Regulatory Regime at National and Regional Level

Over the years, the regulatory regime in different countries has emerged at different pace and has taken all different directions. The national responses have largely been driven by specific national situations. For instance "mad cow disease" in European situation led to extreme consumer rigidity for genetically modified food. Annex 1 briefly depicts the evolution and current shape of biosafety policy across various countries.

The European Community (EC) introduced an approval system for the deliberate release of GMOs in the environment. In the following years, the labelling of GMOs was made mandatory. This included foodstuffs and food containing additives or flavourings that have been genetically modified. Gradually, now even animal feed has to be mandatorily labelled. These initiatives of the EU have created a large public debate world over. However, the European Commission has reserved the right to support biotechnology research. The Commission has also acknowledged that Europe's biotechnology industry is lagging behind. In fact, a four-prong strategy has been worked out to catch up in this technology race.[9]

Apart from EU, Japan has also come out with stringent regulations. A committee in charge of developing rules for biotechnology labelling was appointed in 1997 under the Ministry of Agriculture, Forestry and Fishery (MAFF). This ministry has announced to introduce mandatory safety checks to guard against imports of unapproved genetically modified crops for human consumption as well as animal feed.[10] This almost has set in a zero tolerance for food imports containing unapproved gene spliced products.

As the global debate over the benefits and safety of genetically modified food rages on, China has passed regulations that require clearer labelling of these types of products. Now it is being proposed that China would introduce mandatory labelling of food. China's State Council considered and passed the Regulations Concerning the Biotech Safety Management of Agricultural Gene Alteration. In the past, when crops with genetic alterations graduate from the laboratory to the field, they had to be approved by the Ministry of Agriculture. However, when they were transformed into merchandise, there were no such regulations. The new legislation will regulate the biological products with gene alterations requiring the above-mentioned food labelling, for example, so that the issues related to gene alteration can meet international standards.[11]

In India, though biosafety policy evolved in last decade, it has yet to address trade-related issues. The policy was announced in 1990 and then subsequently revised. However, the issues like imports of genetically modified goods are now being further strengthened. One of the recent controversies which highlighted this lacuna was related to import of genetically modified soybean from the US by a donor agency serving food programme for children.[12] India's Biosafety and Recombinant DNA Guidelines (1990) fall under the Environment (Protection) Act of 1986. In 1994, after India signed the Convention on Biodiversity, the DBT revised its earlier guidelines to accommodate the safe handling of GMOs in research, application and technology transfer. This includes the large scale production and deliberate release of GMOs plants, animals and products into the environment. Guidelines are also provided for the shipment and importation of GMOs for laboratory research.

In India the most important committees are: the Institutional Biosafety Committees (IBSC), responsible for the local implementation of guidelines, the Review Committee on Genetic Manipulations (RCGM) responsible for issuing permits; and the Genetic Engineering Approval Committee (GEAC), responsible for monitoring the large scale and commercial use of transgenic materials. These committees have statutory authority. Most of the committee members are from the scientific community and the staff of Department of Biotechnology (DBT) and the Ministry of Environment and Forestry (MoEF). DBT appoints the members to the committees. The GEAC is supposed to be assisted by the State Biotechnology Coordination Committees (SBCC) and District Level Committees (DLC). However, several states are still in the process of establishing SBCC and DLC committees. Efforts are being made to technically equip the members of these committees with information and literature.

WTO and Trade Implications

The issue of GMO possibly span several WTO agreements, including SPS, Agriculture, Trade-related Aspects of Intellectual Property Rights (TRIPs) and Technical Barriers to Trade (TBT). They GMOs related issues have also been discussed in the Committee on Trade and Environment (CTE). Although member governments have notified a large number of regulations related to GMOs to the SPS Committee, most of the discussion on the subject has been in the TBT Committee with the focus on labelling regulations. In the current agriculture negotiations, some members have called for clarity in the WTO rules as applied to products of new technologies.

The SPS Committee, meeting on October 31 and November 1, 2001, for the first time discussed Genetically Modified Organisms. In considering notifications for the first time in the SPS Committee, the US and Canada enquired about the EU's restrictions on Genetically Modified Organisms (GMOs). They complained that the EU had failed to notify its latest directives on traceability and labelling under SPS, even though these indicate that health protection is one of the objectives. The EU delegate mentioned that any comments on this notification should be sent to its authority handling technical barriers to trade issues. Under "other business", the US also complained about the lack of scientific justification for the EU's continued de facto moratorium on approval of GMO products, and Canada said that the latest EC measures discriminate against products produced by GM technology, even where no trace remains in the final products.

In the TRIPs Committee, it is the Article 27 which has remained at the centre of focus. Article 27 of the TRIPs Agreement defines the types of inventions, which have to be eligible for patent protection and those which can be exempt.These include both products and processes, and they cover all fields of technology.

The Article 27.3(b) covers biotechnological inventions. It is currently under review in the TRIPs Council, as required by the TRIPs Agreement. Some countries have broadened the discussion to cover biodiversity and traditional knowledge. India and many other developing countries have been demanding an explicit position on benefit sharing on traditional knowledge system. The Doha Ministerial statement said:

> "We instruct the Council for TRIPs, in pursuing its work programme including under the review of Article 27.3(b), the review of the implementation of the TRIPs Agreement under Article 71:1 and the work foreseen pursuant to paragraph 12 of this declaration, to examine, inter alia, the relationship between the TRIPs Agreement and the Convention on Biological Diversity, the protection of traditional knowledge and folklore, and other relevant new developments raised by members pursuant to Article 71.1. In undertaking this work, the TRIPs Council shall be guided by the objectives and principles set out in Articles 7 and 8 of the TRIPs Agreement and shall take fully into account the development dimension."

Broadly speaking, Article 27.3(b) allows governments to exclude plants, animals and "essentially" biological processes (but micro-organisms, and non-biological and microbiological processes have to be eligible for patents). However, plant varieties have to be eligible either for patent protection or through a system created specifically for the purpose (*"sui generis"*), or a combination of the two. For example, countries could enact a plant varieties protection law based on a model of the International Union for the Protection of New Varieties of Plants (UPOV). The review of Article 27.3(b) began in 1999 as required by the TRIPS Agreement.

The topics raised in the TRIPs Council's discussions include: the pros and cons of various types of protection for new plant varieties (patents, UPOV, etc); how to handle moral and ethical issues (e.g. whether invented life forms should be eligible for protection); how to deal with traditional knowledge and the rights of the communities where genetic material originates (including benefit sharing when inventors in one country have rights to creations based on material obtained from another country); and whether there is a conflict between the TRIPs Agreement and the UN Convention on Biological Diversity (CBD). At WTO some developing countries including India have also suggested that patent applicants disclose the origin of genetic material used, which would make benefit sharing easier to implement. These countries have also emphasized on benefit sharing through prior agreement between the researchers and the host country where the genetic material originates.

However, some countries are seeking clarification on issues such as the meaning of the term "micro-organism" and the difference between "biological" and "microbiological" processes. Some countries say that life forms and living creatures should not be patented and that ethical questions should also be discussed. Some developing countries want to make sure that the TRIPs Agreement takes account of more specific concerns such as allowing their farmers to continue to save and exchange seeds that they have harvested, and preventing anti-competitive practices which threaten developing countries' "food sovereignty".

The pertinent question is what agenda developing countries should pursue and to what extent it is technologically tenable.[13] An answer to this should only guide the future course of action for the developing countries, not only with respect to the TRIPs negotiations but also their IPR policy in general. In this context, it needs to be mentioned at the outset that the increasing importance of genetic engineering in agricultural research across the world, a continued increase of Genetically Modified Organisms (GMOs) and the ability to patent plants has actually reduced the importance of plant variety protection and consequently of the *sui generis* system within the IPR regime.

Here it would be interesting to take note of the broad trends in the intellectual property regime at the level of individual developed countries. Till recently, life forms used to be exempted from patenting. However, developments in biotechnology are compelling for revising the approach towards the intellectual property regime. These policy changes have largely been taking place in the USA, but now European Union and Japan are also all set to closely follow in this race despite the fact that EU and Japan are opposed to biotechnology. Accordingly, various national governments are bringing in changes in the national laws in order to protect and encourage investments in biotechnology. These policy changes have further widened the scope of the ongoing debate. Now it covers a wide range of issues such as the range of product patents and the patentability of genes, gene-sequences and parts of gene-sequences derived from humans, animals, plants or microorganisms. The added aspect is of the relationship between the patent system and the plant variety system. Moreover, patenting, especially of human body parts, has posed an ethical limit for biotechnology itself. In the following sections we attempt to analyse some of these prominent trends in the patenting regime.

The Plant Variety Protection (PVP) and the patents are the two important forms of intellectual property rights. In context of developing countries, PVP has been there for some time but patents for plants is a recent phenomenon. Both patents and PVP provide exclusive monopoly rights on the creation for commercial purposes over a period of time. A patent is a right granted to an inventor to prevent all others from making, using, and/or selling the patented invention for some years. The criteria for a patent are novelty, inventiveness (non-obviousness), utility, and reproducibility. Although patents were designed for industrial application, with biotechnology patent offices now grant patents on micro-organisms and, in some countries, on all life forms.

The intellectual property regime for plant variety protection emerged with a strong commitment for public interest in mind. The whole provision for compulsory licensing was introduced with this intention only. Under this provision of compulsory licensing, a holder of plant breeders' rights can neither refuse any applicant nor can offer unreasonable terms for this. Plant variety protection has worked well as a mechanism to promote the interests of the plant breeders for developing new varieties through giving them proprietary rights on the one hand and as a custodian of public rights of access and use of genetic material on the other. PVP gives patent-like rights to plant breeders. What gets protected in this case is the genetic make-up of a specific plant variety. The criteria for protection are different: novelty, distinctness, uniformity, and stability. PVP laws can provide exemptions for breeders, allowing them to use protected varieties for further breeding, and for farmers, allowing them to save seeds from their harvest.

In plant breeding, thus, PVP is the weaker sister of patenting mainly because of these exemptions. PVP also encourages cross licensing between a holder of PVP and a holder of a patent. Under the breeders' exemption of plant variety rights, anyone may use protected material for breeding purposes. However, the patent regime does not reciprocate this.

Impact on Trade

As is clear, though international trade regime at WTO has yet to address challenges emanating from advancements in biotechnology, the prohibitive measures have already started affecting the trade. Table 1 shows how US export of corn and soybean has declined in several of those countries which have resorted to these prohibitive tactics. In 1997 import of Corn from European Union was 1000 metric tonnes, which declined to 0.07 metric tonnes by 2000. Similarly, import of Soybean from EU has declined from 8000 metric tonnes in 1997 to 6000 metric tonnes by 2000. Apart from this, delays in authorization to import some Bt corn from the US by France cost US exporters about $300 million in exports to the European Union (Cunningham *et. al.* 2000). Only about 2 million tonnes of the 42 million tonnes of US corn exports went to the EU in 1997. In 1998, only 0.3 million

Table 1: US Exports of Corn and Soybeans to Selected Regions/ Countries, 1997-2000

	Corn (10^6 metric tones)*			Soyabeans (10^6 metric tones)		
Region/ Country	1997 Jan-Dec	1999 Jan-Dec	2000 Jan-Dec	1997 Jan-Dec	1999 Jan-Dec	2000 Jan-Dec
Africa	3.95	6.69	6.46	0.11	0.28	0.23
Asia	27.68	31.45	26.73	11.68	12.14	14.94
European Union	1.56	0.09	0.07	8.96	6.46	6.10
Japan	15.45	15.33	14.87	3.70	3.68	3.58
South Korea	3.44	6.16	2.29	1.25	1.17	1.34
Canada	1.03	0.97	1.49	0.26	0.33	0.33
China (Taiwan)	5.44	4.73	4.72	2.27	1.95	1.93

* 1 metric tonne = 2,204 pounds.

Source: ERS/ USDA. FATUS Report. Available online at http://www.ers.usda.gov/db/fatus/

tonnes of the 41 million tonnes went to the EU. Factors that have been used to explain the declines include bans of GM corn by France, Austria and Luxemburg (Cunningham *et al.* 2000). Similar declines have been documented for soybeans. Only 9 million tonnes (out of 26 million tonnes) of US soybean exports went to the EU in 1997 and only 6 million tonnes (out of 20 million tonnes) were exported to the EU.

Some developing countries like India have recently gone through very tough time in terms of governance of biotechnology.[14] Genetically modified cotton was initially illegally introduced in the production system, which is all set to create problems in those countries where imports of GM variety are banned, a problem similar to what we mentioned in case of US. However, as Table 2 shows, total impact on exports of only those crops in which biotechnological applications have been planned, for instance, cotton, corn, soybean and vegetables to only three countries would be $6201 million in case of India. It would nearly be $1700 million to the EU alone. The situation becomes much more challenging when one realises that there are very few equipped laboratories in which GMO testing can be done. Therefore, a clear market strategy and options with technological choices would have to be made with a lot of precaution.

Table 2: India's Exports of (Potential GM) Crops

(US $ Million)

	Cotton	Corn	Soyabean	Vegetables	Tot Crops imported by countries	% Share In Total Exports of Crops
EU	1725.64 (28.99)	0.05 (2.27)	0.08 (32.00)	41.44 (16.77)	1767.21	28.50
Japan	161.79 (2.72)	—	0.11 (44.00)	1.36 (0.55)	163.26	2.63
South Korea	189.03 (3.18)	—	—	0.52 (0.21)	189.55	3.06
Total	**5951.7**	**2.2**	**0.25**	**247.07**	**6201.22**	**100.00**

Source: India Trade 2001.
Note: Figures in Parenthesis are percentage share in total exports.

At the Committee on Agriculture this issue came up again in the same context. In a special session of the Committee on Agriculture, the European Union tabled a controversial paper on food safety, proposing criteria for the application of precaution under the Agreement on Sanitary and Phytosanitary Measures (SPS) that would serve as a guideline for panelists in future disputes. According to the EU, the issue needs to be addressed to avoid the public perception that the WTO requires members to force consumers to accept unsafe food. The EU, other European countries, Japan and Korea argued that Article 5.7 of the SPS Agreement should be clarified through an understanding that would send the right signals to consumers.

Article 5.7 allows members to take provisional health measures when relevant scientific evidence is insufficient, and the substance of the discussions revolved around whether the Article was clear enough to maintain the balance between the need for consumer protection on the one hand and the need to avoid disguised protectionism on the other.

To create predictability for members and to prevent Article 5.7 from being abused for protectionist purposes, the EU proposed that precaution be applied according to the following five criteria: (i) the measure should not be discriminatory; (ii) it should be aimed at achieving consistency in the level of protection that the Member has chosen; (iii) the adopted measure should presuppose an examination of the benefits and costs of action and lack of action; (iv) it should be reviewed if new scientific information is obtained; and (v) the measure must be based on scientific evidence provided by qualified and respected sources, but not necessarily by the majority of the scientific community. The US and many developing countries strongly opposed this effort to bring food safety onto the agriculture negotiating agenda. They argued that the EU's version of the precautionary principle was based on political rather than scientific considerations. Suspecting that the EU was chiefly interested in finding another avenue for addressing the controversial precautionary principle in the WTO, the US, the Cairns Group and India took a position that instead of the agriculture negotiations, food safety should be discussed at the SPS and the TBT Committees.

Concluding Remarks

The entry of biotechnology especially in the post-green revolution scenario when agriculture production seems to pose several challenges, the concerns like food security assumes key importance in the context of developing countries. The opinion about biotechnology among the developing countries is mixed. There are experts who actually enlist several factors why biotechnology per se is not the right technology to ensure food security and reduce poverty in the developing countries. They even go up to the extent of saying that biotechnology is a technology that has been shaped by a narrow range of private interests – interests that are incompatible with the demands of an ecologically sound and socially-just agriculture. Thus, the issues that the advent of this technology raises, cover a much wider canvass. The ethical dimension of the Genetically Modified Organisms have further confounded the ongoing confusion on the relevance of biotechnology for the developing countries.

In the last decade or so, the transnational corporations have emerged as a major source of biotechnology products. This trend has, probably, further contributed to the concerns among the developing countries as reports about bio-piracy become galore. These concerns have got reflected in the sharper debate being initiated to assess the relevance of this technology for developing countries.

In such a scenario it may not be entirely misplaced to observe that, since biotechnology is a frontier technology, upcoming in a dynamic international environment, it probably requires an altogether different approach to ensure the growth of the technology along with the desired socio-economic goals. Thus, it poses a two-fold challenge: on one hand, the growth of technology has to be ensured and on the other, policies would have to be evolved not only to restrict its adverse implications but also for ensuring growth in the agricultural sector. Any imbalance between the two may offset the wider developmental impetus, the agricultural sector needs at this point. It is high time that agricultural R&D plans prioritise investment on new technologies so as to rightly balance or rather supplement the traditional techniques with new technologies to serve socio-economic interests.

The emerging trade regime under WTO has influenced international trade to a great extent. These changes have severe implications for the developing countries. More so when they are already struggling with the implementational hurdles of the TRIPs regime. There are many developing countries, which have yet to put in place national legislations to position themselves vis-à-vis the international negotiations at the WTO. Several of them come out with several drafts of biodiversity and patent laws but they have yet to see light of the day. There have been various reasons for this delay but now it seems to be clear that it would not only adversely affect the access to technology but also the patenting of research tools would also exclude the late comers in the technology race from imitation or even from product development in any other form.

The WTO TRIPs regime article 27.3 (b) refers to have either a patent regime or an effective *sui generis* system for protection of plant varieties. In the last decade or so, the developing countries have strongly debated the various aspects of *sui generis* system and what actually constitutes it. However, as is evident from the earlier sections, the varietial protection is being attempted through much more stronger patent regime, which do not allow any kind of exemption and is much narrower in its scope than the plant patents or plant variety protection. There is a continuous growth in what is called the utility patents in the US and the Biotechnology Directive of EU has suggested a similar mechanism for the protection of biotechnological inventions in Europe. Along with this there is also a growing trend of patenting the research tools as well. Thus, in light of the developments in biotechnology, the profile of patent regime is fast changing in the developed countries. Needless to mention that a large part of this research is emanating from the private sector.

The above analysis shows that it is desirable that developing countries would make choices in the biotechnology at selective levels. Even within agricultural biotechnology there are several options which take the horizon far ahead of adoption and diffusion of GMOs alone. This decision should be subject to a critical evaluation of the need assessment of developing countries. In order to obtain benefits and be competitive in biotechnology, developing countries need to access not only the products but, more importantly, to the technology and certainly the tool for it.

In addition, access to genetic resources and the associated traditional knowledge plays a role, highlighting the need for benefit sharing and prior informed consent. At another level, there has to be a multilateral effort to help build capacity related to institutions, infrastructure, policy development and implementation, human resources, local-level ecological data, and research and development in the developing countries in general and in underdeveloped countries in particular. These countries also require support to adopt GM product along with provisions for its safe use and capability to handle its importers and exporters. As far as international negotiations are concerned, a strategy founded on well-informed opinion on technical aspects should be evolved. This includes participation in international negotiations at the WTO and international standard-setting organisations.

As is clear, biotechnology has great potential to be used as commercial technology and thus would be capable of generating a profit exclusively for its owner and others who may be able to access its conditionally at a very high cost. The access is also determined by the terms and conditions set by the IPR Regime. In case of biotechnology, TNCs have a far stronger monopoly than any time before in the history of agriculture science. As biotechnology is an emerging technology, the owners guard the source of their competitive advantage to the core. In some cases they may internalize transfer of technology, within their network of affiliates rather than externalising such a transfer to unaffiliated licensees.

This scenario completely rules out any possibility of deploying conventional instruments for transfer of technology. The developing countries would have to reconsider their technology policy to encourage and support innovation in the field of frontier technologies. For this they may have to improve upon the existing technological base. In fact, the need is to set their own R&D agenda in the realm of biotechnology. As at present R&D plans are not based on the economic requirements of respective developing countries. Since this is highly capital-intensive technology, the developing countries may consider to pool their resources for creating common facilities like Gene Banks, instruments for marker assisted technology, etc.

Endnotes

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Annex 1: The Regulatory Framework Regarding GMOs : Selected countries

EU	**1990** -	EC introduced an approval system for the release of GMOs into the environment for experimental and commercial purposes.
	1997 -	EC made labelling mandatory for a product containing GMOs.
	1999 -	EC provided consent to place GMOs in the market for a limited period on the condition of compulsory monitoring.
	-	labelling requirements extended to include foodstuffs and food containing additives or flavouring that have been genetically modified.
	2000 -	a directive was introduced that will include a requirement for animal feeds to be labelled.
	-	need for prior consent of third countries that are importing GMOs.
	2005	was set as a definitive date for phasing out the use of GMOs that are resistant to antibiotics.
Japan	**1999** -	Japanese government recognized 22 GMOs as "safe products. All imports containing GMOs other than the approved ones to be rejected.
	2000 -	Japan introduced mandatory labelling requirements for final products containing GMOs.
	-	Japanese government circulated the official definition of organic farm products. GM products are among the products that cannot be labelled as organic.
United States	**1996** -	US government approved some 50 varieties of genetically modified crops.
	1999 -	A bill requiring labelling of all genetically modified entity was introduced, but the issue remains unresolved up till now.
	2000 -	A proposal was introduced by the FDA under which biotech would notify them four months in advance before marketing a new GM product and provide evidence of the safety of that product. This, however, is not mandatory it is followed on voluntary basis.
	-	the FDA released its proposed final rule for definitions of organic foods. Any food labelled 'organic' could not have been developed using GMOS.
New Zealand	**1999** -	a pre-market safety assessment to be carried out by the food authority before genetically modified food are sold.
	-	Introduced labelling of such products.

Annex 1 continued

Annex I continued

Australia	1999	-	a pre-market safety assessment to be carried out by the food authority before genetically modified food are sold.
		-	Introduced labelling of such products.
Canada	1999	-	the Canadian Council of Grocery Distributors agreed to develop a voluntary GM food labelling regime.
Thailand	1994	-	Thailand's legislation on plant quarantine was expanded to cover GMOs. Under this, the release into the environment and the import of GM seeds and crops was subject to strict approval system.
	2001	-	The Thai food authority intends to impose labelling requirements.
Sri Lanka			The National Food Advisory Committee is considering the possibility of imposing a ban on the import of GMOs and GM foods.
Republic of Korea	2000	-	passes a legislation regarding mandatory labelling of genetically modified soyabeans, corn, and soyabean sprouts.

Domestic Import Regulations for Genetically Modified Organisms and Their Compatibility with WTO Rules

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Heike Baumüller*

While the estimated global area of transgenic or genetically modified (GM) crops continues to increase the vast majority of acreage (99 per cent) remains confined to just four countries, namely the US, Argentina, Canada and China. In most developing countries it is still not legal to plant GM crops on a commercial basis, largely due to hold-ups in the approval process. Even countries that have in the past moved rapidly on the adoption of GM organisms (GMOs), including China and Argentina, are now slowing down the approval processes. While the regulatory blockages are usually justified on biosafety grounds, trade concerns appear to play an increasing role with countries fearing export losses in markets such as the EU, Japan and Korea where the import regulations for GMOs continue to be tightened. The ongoing trade dispute between the US and the EU's continued *de facto* moratorium on the approval of new GMOs is also adding to the prevailing uncertainty in the international commodities market.

In this context, the first part of this paper will outline regulations affecting the import of GMOs and GM products in selected countries, including import

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restrictions, risk assessment provisions and labelling requirements. While most of the attention will focus on some of the major OECD countries, including the EU, the US and Australia/New Zealand, the paper will also review regulations in key developing countries in Asia, Latin America and Africa. The second part will look at possible conflicts between national import regulations and WTO rules, in particular regarding the current and proposed EU regulations. To this end, the section will briefly outline the relevant WTO agreements; assess the trade-restrictiveness of mandatory traceability and labelling requirements; evaluate whether GMO regulations covering substantially equivalent GM products might be trade-discriminatory; look at the role of precaution as a justification for an import ban on GMOs, and briefly discuss the Cartagena Protocol on Biosafety and how its provisions might impact on a possible dispute at the WTO.

Review of Selected Domestic Import Regulations for GMOs

European Union

The EU has set up the most stringent import regime for GMOs worldwide. Applications for the approval of GMOs for release into the environment or placing on the market must be accompanied by a full risk assessment which should identify and evaluate potential negative effects of the GMO, direct or indirect, immediate or delayed, also taking into account the cumulative and long-term effects on human health and the environment. This procedure has recently been strengthened under the revised Directive 2001/18/EC on the environmental release of GMOs, which entered into force on October 17, 2002. In particular, the 2001 Directive introduces mandatory information to the public, including information on notifications, assessments and releases of GMOs, and general rules on mandatory labelling and traceability at all steps of market placement.

While mandatory labelling requirements for food and food ingredients, which contain or consist of GMOs, have been in place for some time, they have recently been tightened under new traceability and labelling regulations adopted in July 2003. The regulations require all GM food and feed to be labelled, irrespective of whether the GM material can still be detected. In contrast, under the previous rules, GM foods derived from, but no longer containing GMOs, which are substantially equivalent, and GM feed had not been subject to labelling requirements. As a result of an ongoing *de facto* moratorium, no commercial releases of GMOs have been approved since 1998 following calls by a number of European countries for the suspension of new authorizations pending the adoption of the revised rules on labelling and traceability of GMOs and GMO-derived products.

USA

In contrast to the EU, the US has not developed separate regulations for biotechnology, but rather regulates GMOs through existing legislation. While no mandatory risk assessment requirements for GMOs exist, the proposed *Premarket Notice Concerning Bioengineered Foods* will require companies to submit information on safety considerations before marketing GM foods. Regarding labelling, the US Food and Drug Administration have issued voluntary draft guidelines for the labelling of GM foods. In addition, efforts are currently underway in the states of Oregon and California to introduce mandatory labelling requirements for GM foods and transgenic fish respectively, while draft legislation requiring the labelling of GM foods was introduced in the House of Representatives in May 2002.

Australia/New Zealand

Australia has one of the most developed regulatory systems for GMOs. All 'dealings' with GMOs are regulated by the *Gene Technology Act (2000)*, which, *inter alia*, set up the office of the *Gene Technology Regulator* charged with monitoring and enforcing the legislation. Safety assessment and labelling of GM foods are governed by Standard A 18, developed jointly with New Zealand, which sets out some of the strictest labelling requirements in the world. In particular, the Standard requires all foods produced using gene technology to be assessed regarding safety for human consumption and approved before sale and use. The Standard furthermore requires all GM food and ingredients to be labelled where they contain novel DNA and/or novel protein in the final food, or have altered characteristics. However, in contrast to the proposed EU regulations on labellling and traceability, GM foods derived from but no longer containing GMOs are exempt from labelling. While Australia has approved four GM crops for commercial release and is conducting various field trials, New Zealand has placed a moratorium on the environmental release of GMOs until 31 October 2003.

Asia

In Asia, the only major GM crops approved for commercial release are Bt cotton, which is grown commercially in China, India and Indonesia, and GM corn recently approved in the Philippines. To date, no Asian government has given official permission to plant GM soybeans or rice. While China had initially moved quickly on the approval of GM crops for environmental and commercial releases, the approval process has slowed considerably since 2000 and strict regulations have been implemented for GMO imports. For its part, Japan requires all recombinant DNA (rDNA) organisms to which new properties have been introduced using rDNA technology to undergo a safety evaluation, which should be submitted to the Ministry for Agriculture, Forestry and Fishery for approval. In addition, certain GMO agricultural products need to be labelled. Korea's Ministry of Agriculture & Forestry requires mandatory labelling for certain GM "raw materials", including GM soybean, corn and beans sprouts as of 1 March 2001 and GM potatoes as of 1 March 2002. In April 2002, the Philippines adopted regulations for GMOs, which will require importers of GM plants for environmental release, and GMOs for food, feed and processing to acquire a permit as of 1 July 2003.

Several other countries in the region have also made efforts to control imports of GMOs. In 2001, Thailand banned all GM field experiments and has restricted GM imports, most recently in February 2002 when the country banned the import of 37 more GM plants in addition to the 40 already listed. Efforts are also underway to implement labelling regulations for a number of soy and corn products. Malaysia, while investing heavily in the development of GM crops since the 1980s, is also holding back on the commercial release of GM crops. On 1 May 2001, Sri Lanka's Health Ministry imposed import restrictions requiring 21 categories of food imports to be free of GM products. The ban was later suspended following a request by the WTO that the country should give its trading partners 60 days to prepare for the restrictions, before it was finally postponed indefinitely. India had not approved the commercial planting of any GM crops until

March 2002 when the Indian Genetic Engineering Approval Committee finally approved the commercial production of three varieties of GM cotton amid widespread protests by anti-GM activists.

Latin America

In Latin America, Argentina is the world's second largest producer of GMOs after the U.S., and is by the far the biggest player regarding the commercialization of GM crops. Argentina's regulations set out a number of requirements, which must be met in order to permit the release of GMOs into the environment; these are taken into account by National Advisory Commission on Agricultural Biotechnology (CONABIA) when evaluating each application. In order to obtain the appropriate marketing licence, varieties must also comply with requirements stipulated by the National Service of Health and Agrofood Quality (SENASA) regarding human and animal consumption.

In contrast, several other important agricultural states in the region, notably Brazil, have yet to officially approve the commercialization of GM crops, even though illegal planting of GMOs is thought to be widespread in some areas. The Brazilian Biosafety Law, which applies to all GMOs whether used for release into the environment or for human or animal food processing, prohibits the entry of GMOs into Brazil without prior approval. Only one GM crop – Monsanto's Roundup Ready soybeans – has been approved for commercial release by Técnica Nacional de Biosseguranca (CTNBio). However, an injunction on the commercial planting of the soybeans in Brazil has been in place sicne 1999 and government approval of the commercial release of GMOs has been put on hold.

Concerns have also repeatedly been raised in Mexico regarding the importation GM corn. These concerns were further fuelled by recent findings that Mexican native varieties of corn grown in remote regions of Mexico have been contaminated by transgenic DNA despite a ban imposed in1998 on the planting of GM corn. This discovery led the Mexican Congress, environmental groups and farm organizations to call on the government to ban the importation of GM corn. For its part, Bolivia imposed a ban on the imports of GMOs in January 2001, which was revoked in October 2001, allegedly due to pressure by the Argentinean soy corporate sector.

Africa

Only South Africa and Zimbabwe have put in place a biosafety law. Many other countries in African have developed, or are in the process of developing, biosafety polices and laws to comply with the requirements of the Cartagena Protocol on Biosafety. Kenya, for instance, adopted regulations and Guidelines for biosafety in Biotechnology in 1998, which charge the National Biosafety Committee, set up in 1996, with the approval of GMO imports. Egypt's regulations, adopted in 1995, required an advance permit for importation of genetically engineered materials. Both Nigeria and Kenya are also in the process of developing their national biosafety regulations. Most African countries, however, still need to put into force legislation concerning existing policies.

Efforts are also underway at the regional level to establish biotechnology-related policies, including the Southern African Development Community (SADC), the Common Market for Eastern and Southern Africa (COMESA) and the New Partnership for African Development (NEPAD). Furthermore, the Organisation of African Unity has developed a draft African Model Law on Safety in Biotechnology to serve as a basis for formulating national biosafety laws. However, no country has implemented the draft Model Law to date.

Only South Africa has so far approved the commercial growing of GM crops. While research and testing on similar products is being conducted in other African countries, the approval of GM crops for commercialization and import of GM commodities continues to be extremely slow.

Compatibility between Domestic GMO Import Regulations and WTO Rules

Biotechnology-related concerns are increasingly cropping up in trade discussions, both at the World Trade Organization (WTO) and in other forums. In May 2003, the U.S., together with Argentina, Canada and several other countries, initiated WTO dispute settlement proceedings against the EU's *de facto* moratorium on the approval of new GMOs and a number of marketing and import bans in certain EU member states. WTO Members have also raised concerns over domestic import regulations for GMOs, including in the EU and China, in the Committees for Sanitary and Phytosanitary Measures (SPS) and Technical Barriers to Trade (TBT). Besides, the U.S. is reported to have raised the possibility of a WTO challenge with regard to GMO regulations in Sri Lanka, Bolivia and Croatia.

How the U.S.-EU dispute will play out is hard to predict at this early stage in the proceedings. Similarly, the outcomes of a possible challenge to a country's traceability and labelling scheme for GMOs are difficult to forecast given that so far no mandatory labelling scheme has been formally challenged at the WTO, let alone one related to GMOs. The following discussions aims to outline some of the arguments that might be raised for or against some of the described import regulations and measures, and how these arguments might fare if scrutinized by a WTO panel. The analysis is neither meant to be exhaustive nor legally thorough, but rather aims to raise some points for consideration. Also, much of the discussion will necessarily focus on the EU regulatory system as those rules have attracted most attention, but the conclusions are equally valid for many other import regulations.

What Are the Relevant WTO Agreements and How They Apply to GMO Import Regulation?

The Agreements on the Application of Sanitary and Phytosanitary Measures (SPS) and on Technical Barriers to Trade (TBT) are applicable to GMO import regulations. The SPS Agreement applies if the measures were aimed at the protection from food safety risks or from damage caused by pests. Any such measures should either be based on international standards or on a risk assessment. The TBT Agreement applies to product requirements that are mandatory (technical regulations) as well as voluntary (standards) and to conformity assessment procedures not covered by the SPS Agreement. Also of relevance is the General Agreement on Tariffs and Trade (GATT), which deals with trade in goods and contains several provisions; for example those referring to non-discrimination and quantitative restrictions, that are relevant to the trade in GMOs. Furthermore, Article XX sets out a number or exceptions, allowing Members to take measures which would otherwise violate GATT rules to, *inter alia,* protect public morals, human, animal or plant life or health and to conserve exhaustible natural resources (Article XX(a), (b) and (g)).

Are Mandatory Traceability and Labelling Requirements Unnecessarily Trade-restrictive?

Both the SPS and TBT Agreements require measures that are not more trade-restrictive than necessary in order to fulfill the objectives of the Agreements. Regarding the European Commission's proposed traceability and labelling regulations, the U.S. and other countries have argued in the past that the rules would be unnecessarily trade-restrictive, and that less trade-restrictive measures could be put in place to achieve the desired objectives. Often cited in this context are the costs of segregating modified from non-modified products, monitoring a particular crop throughout the food chain (e.g. by using identity preservation systems), and testing for the presence of GM materials to comply with the threshold of one per cent for the accidental presence of GMOs as proposed by the Commission. Also, the magnitude of additional costs is not fixed and is likely to change as the industry adapts to the traceability requirements and as the volume of material involved increases. Also, standards for foods derived from biotechnology adopted by the Codex Alimentarius Commission in July 2003 include the "tracing of products" and food labelling as risk management tools. Some see these standards as a major breakthrough in international negotiations on the use of traceability systems that at least partially vindicate the EU's insistence on introducing such requirements for GM food.

Are Import Regulations Covering 'Substantially Equivalent' GM Products Trade-discriminatory?

The TBT Agreement stipulates that Members are not allowed to give less favourable treatment to any products "than that accorded to *like* products of national origin and to *like* products originating in any other country" (Article 2.1, emphasis added). Some argue that import regulations that impose special risk assessment, traceability and/or labelling requirements for 'substantially equivalent' GM products might contravene this provision as they discriminate against 'like' products. Under the proposed EU regulations, all food and feed derived from, but no longer containing GMOs that are substantially equivalent to their conventional counterparts would also be subject to traceability and labelling requirements. If the EU were to justify these regulations as a legitimate objective (e.g. consumer information) under the TBT Agreement, they would be required to show that the measures do not run counter to the non-discrimination provision for 'like' products. According to established practices under the General Agreement on Tariffs and Trade (GATT), likeness is determined on a case-by-case basis according to four criteria; the products' physical properties, end-uses, tariff classification and consumers' tastes and habits. Given the strong physical similarity between traditional foods and substantially equivalent GM foods, the latter are likely to be viewed as 'like' under the first three criteria. The EU would thus need to show that consumers' perceptions and behaviour affect the degree of substitutability and competitiveness in the market-place.

While the SPS Agreement does not include a 'like' product provision the EU might still find it challenging to show that such products might pose health risks (in particular with regard to feed) given the widespread application of the 'substantial equivalence' concept, including Codex standards, or that the measure was necessary to prevent the spread of pests. Similar considerations apply if the EU were to justify its regulations under the exceptions of GATT Article XX.

Could a Ban on Imports of GMOs be Justified as a Precautionary Measures?

The differing approaches to 'precaution' in the EU and U.S. partly lie at the root of the ongoing disagreement between the U.S. and EU over the European *de facto* moratorium on the approval of new GMOs. The concept of precaution is embodied in Article 5.7 of the SPS Agreement. For the EU *de facto* moratorium to be justifiable under Article 5.7, it would need to constitute a provisional measure and the EU would have to demonstrate that it was actively seeking "to obtain the additional information necessary to make a more objective assessment of risk" and review the SPS measure "within a reasonable period of time". The moratorium was originally set to stay in place until adoption of traceability and labelling regulations. Thus, the EU's ability to justify the *de facto* moratorium by invoking the precautionary provisions of the SPS Agreement might depend on whether the EU will indeed resume approvals once the traceability and labelling regulations enter into force later this year. The EU might also invoke the 'precautionary principle' as a customary rule of international law, rather than refer to Article 5.7, if the measure is not intended to be provisional. It remains unclear, whether the principle constitutes an established principle under international law. Recognition of its status as a general principle would be relevant for the outcomes of a WTO dispute as such principles would be taken into account in the interpretation of relevant WTO provisions.

How Might the Cartagena Protocol on Biosafety Impact on Possible WTO Disputes Related to GMO Import Regulations?

The *Cartagena Protocol on Biosafety* – adopted in January 2000 under the Convention on Biological Diversity and set to enter into force on 11 September 2003 – regulates "the transboundary movement, transit, handling and use of biological diversity, taking also into account risks to human health". The Protocol applies to two categories of living modified organisms (LMOs), namely LMOs for "intentional introduction into the environment of the Party of import" (e.g. seeds intended for planting) and LMOs "intended for direct use as food or feed, or for processing" (e.g. soybeans for use in food), and sets out the different notification and approval procedures for the two categories. Once the Protocol has entered into force Parties to the Protocol, whose import measures are challenged at the WTO, might justify these regulations by referring to the Protocol's provisions, including notification and labelling requirements and import restrictions covered by the Protocol. The Protocol could also be of relevance in future disputes with regard to the use of precaution. In particular, the Protocol contains what many see as the first operationalization of the precautionary principle in the body of an international environmental agreement. However, when the Protocol was adopted, several issues remained unresolved and were left to the Conference of the Parties to be finalized once the Protocol has entered into force, including requirements for identifying shipments of LMOs for direct use as food, feed, or for processing and standards for the identification, handling, packaging and transport practices.

Policy and Development of Biotechnology: Bangladesh Perspective

N. Choudhury*

Science Policy

One of the dictionary meanings of policy is the statement of aims and ideas. The other meaning is plan of action. I am not sure whether most of the policy documents state about the mechanism of implementations of aims and objectives outlined in the policy document. But to a common man policy usually is a nice printed bound volume of pious wishes issued by a government, government agency or even an NGO. A formal science policy was issued by the Government of Bangladesh in 1986. As a statement of policy its contents constituted broad based application of science and technology particularly modern science and technology including biotechnology for national development. At that time poverty alleviation, good governance and women empowerment were not catchy terms. However, economic and social development through application of science and technology were supposed to take care of all related problems. It mentioned about establishment of scientific institutions, upgrading existing institutions and human resource development

Science Policy and WCS

World Science Conference was held in Budapest in 1999. The 12-page document containing 96 paragraphs each of which issued at the end, had

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policy related recommendations distilled into the Para 55(section 2.6) that reads as follows:

National policies should be adopted that imply consistent and long term support to S&T, in order to ensure strengthening of human resource base, establishment of scientific institutions, improve and upgrading of science education, integration of science into national culture, development of infrastructure and promotion of technology and innovation capacities. Interestingly many of the recommendations of WCS coincided with recommendations of our national science policy made 14 years earlier.

Policy and Action-contradiction

The question may arise then why we did not make a significant growth in the S&T sector, what to speak of biotechnology in Bangladesh? The answer is that the broad recommendations in the policy document did not have the adequate analytical framework or implementation strategy for addressing the nature of problems faced by the S&T sector and the recommendations were not based on expenditure, benefits constraints, etc. Science and technology enjoyed rhetorical support from all the successive governments. There were encouraging utterances for S&T development from time to time from political leaders but there were little or no follow up actions to match the words. I believe the political wishes were genuine but there was lack of conscious or unconscious synergy between political will, administrative set-ups and the scientific community. Even ignoring the earlier years, the 5th plan (1999-2002) size was TK. 19590 million of which allocation in S&T was only 8000 million, i.e. 0.41 per cent and only 0.106 per cent of GDP. Thus, in spite of pronounced political commitments when budgetary resource crunch due to short-term shortage arose the first casualty was S&T sector. In fact, S&T Division was upgraded to a ministry once and then downgraded and then a full-fledged ministry was created in 1993. Prior to that it shuttled to different ministries such as education, energy, industry President's Secretariat, etc. All these happened due to one reason, i.e. lack of confidence in the minds of the policy makers that S&T can play an effective role in national economic development. Many economists and planers thought that S&T is a commodity that can be purchased from the international market when needed.

The situation has of course changed over the recent years. The S&T ministry has been given a new shape and name. Now it is called the Ministry of Science and Information & Communication Technology. Allocations have been increased significantly and thrust has been given on IT and BT. In the backdrop of what has been mentioned so far let me discuss situation about biotechnology.

Definition and Prospects

Biotechnology has been defined as the application of scientific and engineering principles to process material (organic or inorganic) by use of biological agents to provide goods and services. The Convention on Biological Diversity defines biotechnology as 'any technological application that uses biological systems, living organisms, or derivatives thereof to make or modify products or processes for specific use'.

The technology based on biological systems-plants, animals and microbes-has been practised for thousands of years through conventional methods and conventional biotechnology still plays a dominant role in providing goods and services. Genetic engineering is the pivot of modern biotechnology. It has opened up wide opportunities for development in different areas of biological sciences and last 15-20 years had been the golden age for biotechnology. Within this short span of time recombinant DNA technology that was hitherto considered a primarily fundamental subject has proved beyond doubt its applicability in many areas of human welfare. Apart from medicine, now biotechnology has been playing vital role in plant improvement, animal health and development, fermentation technology, environment protection and waste management. In medicine its development is spectacular. By now more than 200 newly engineered human pharmaceuticals have been approved for testing in USA alone. Many more are awaiting FDA approval for marketing. Similar is the case for transgenic crops. In USA more than 2000 have already been released for cultivation including soybean, cotton, sugar-beat, rice, wheat, etc. In areas of human health and environment new and significant improvements have been achieved. More and more investments are being made.

In agriculture biotechnology has helped increase in productivity in crops, livestock, fishery and forestry. This technology has helped in controlling pests and diseases through enhanced genetic resistance, improved diagnostics, new vaccines and use of bio-control agents. It thus provides effective tools for enhancing and sustaining food security and poverty alleviation. Excellent prospects exist for improving health of much low-income community by engineering nutritional quality of food, bioremediation and genetic conservation.

Global Scenario

Genetic Engineering Based Products

The following genetically engineered pharmaceuticals are already marketed in US:

a) Blood factor VIII: C
b) Human insulin
c) Human growth hormone
d) Tissue plasminogen activator
e) Alpha interferon
f) Hepatitis B vaccine and
g) Monoclonal antibody to prevent kidney transplant rejection.

New Products Marketed/Under Marketing

1. *Tissue Plasminogen activator (t-PA):* Used for heart attack patients for commercial use. The annual expected sale is about $150 million.
2. *Erythropoiethin (EPO):* Used for cancer.
3. *Interleukin-2 (IL-2):* Used for cancer.
4. *Monoclonal antibodies for detecting and treating Cancer Cells.*
5. *Monoclonal antibodies against septic shock:* The antibodies are destined to eliminate toxic products of infectious bacteria, which persists even if the bacteria are killed. Septic shock is a common cause of death of patients who become infected with antibiotic resistant bacteria in hospitals.

6. *AIDS treatment:* Recombinant alpha interferon, gamma interferon, IL-2, granulocyte macrophage colony stimulating factor (GM-CSF), tumour necrosis factor (TNF), EPO and CD_4 (a T-cell receptor protein to sop up AIDS treatment). More than ten vaccines against AIDS and AIDS related diseases are in various stages of development in the United States.
7. *Genetically engineered bacteria for agriculture:* Monsanto got good results with recombinant bacteria to protect wheat from a fungus. Genetically engineered N_2 fixing bacteria (Rhizobia) was found to contain within the test field. Recombinant insecticidal bacteria of corn showed up good results in field-testing.
8. *Recombinant products for health:* Recombinant beta interferon, gamma interferon, bloods clotting factor VII: C and GM-CSF and have reached market by 1990. By 1991 more and more recombinant therapeutics became commercial products. These include colony stimulating factor, epidermal growth factor, and insulin like growth factor, tumour necrosis factor and several new interleukins. Besides, a number of recombinant vaccines joined the race. Recombinant hepatitis B vaccine is already being sold. New vaccines for measles and pertussis (whopping cough) are on the way. So are for malaria, typhoid and cholera vaccines. Therapeutic human proteins are also on constant increase.
9. *Broadening goals of plant genetic engineers:* Insect and herbicide resistance was the primary goal of plant genetic engineering. New areas like improvement of oil seed crops are also being addressed. Tomatoes to reduce softening during ripening, improvement of key amino acids in forage plants, improvement of rubber production (engineering of rubber transferase gene) are the new avenues opened by genetic engineers working with plants.
10. *Protein engineering:* Recombinant DNA techniques are being used to produce genetically engineered proteins to study their three dimensional structures, effect of amino acid substitution on its shape and function. Big soap and detergent companies are using protein engineering to improve the detergent enzymes. It has its new application in medicine and starch hydrolysis. Knowledge of three dimensional protein structures has also opened up many opportunities

for designing smaller molecules that might act on the proteins. Compounds that block the action of viral proteins, cell receptor proteins, or specific enzymes become easier to design. Both the multinational companies as well as smaller companies are actively engaged in the area.

Transgenic Plants

By using genetic engineering methods more than 3000 plants have been developed with new characters. These are tolerant to freeze, resistant to insects, viruses, fungi, and herbicides. In addition, modification of ripening or softening of fruits shelf life increase of fruits and flowers; and modification of sweetening of fruits have been achieved. In USA, there are more than 2000 genetically engineered corns that have been released for cultivation. Other crops that have been released are Soybean (425), cotton (246), sugar beet (79), rice (54), and wheat (53).

Food Ingredients

Among the numerous microbially derived compounds as food ingredients amino acids, vitamins, sweetening agent (aspartame), organic acids (e.g. citric acid), antimicrobial agents, surfactants, flavour enhancers (e.g. monosodium glutamate) and various enzymes are important. The production of these compounds could be significantly improved through genetic engineering techniques. Vigorous researches are in progress in the advance countries. It is hoped in the near future ingredients derived from recombinant organisms will be available in the market that will balance the ever-increasing demand of the consumers around the world.

Starter Cultures

Saccharomyees cerevisiae (the bakers yeast) is the first genetically engineered starter culture to obtain regulatory approval in the UK in 1990. This strain contains enhanced level of two essential enzymes naturally present in baker's yeast, namely maltose permease and maltase responsible for the production of carbon dioxide that causes 'fluffying' of the bread. It is hoped in the near future more of such strains will be available to use as 'starter culture' in many of the fermented foods.

Peptide Growth Hormones

These are needed for increase milk and meat production. Growth hormone genes could be used to accelerate growth, improve feed efficiency and modify the nutritional quality of meat producing animals, poultry and fish. The peptide hormone bovine somatotropin (BST) has been found to increase the efficiency of dairy cows without altering the nutritional quality of milk. Approval by Federal Drug Administration (FDA) of USA is expected soon. A revolution in milk production is hoped to come with its application.

Improvement of Nutritional Quality

Nutritional quality of food supply could be improved through application genetic technologies. Potatoes with 30 per cent higher solid contents have been developed through gene transfer technologies. The ratio of essential amino acids in the cereal grains has been improved. The technology is contemplated to be used to improve the taste, texture, colour and processing characteristics of raw agricultural products. In future it is hoped that custom designed agricultural products with specific characteristics will be made available through genetic engineering techniques.

Transgenic Animals

Although controversial on ethical point of view, transgenic animals having new characteristics are being produced for increased meat, milk and pharmaceutical products. Human pharmaceuticals are being designed to be produced from animals through their milk, urine and blood. The gene for tissue plasminogen activator (an enzyme that dissolves blood clots in heart attack victims) has been cloned into sheep and cows and the gene is expressed in the milk of the animals. Such animals serve as 'bioreactor' to produce the desired pharmaceuticals and only a few animals would be required to produce the desired pharmaceuticals and only a few animals would be required to produce sufficient quantities for total worldwide use of the compounds. The milk from such animals will, however, not be consumed by human. But, the meat from transgenic animals will need to be consumed for making the process economically viable.

Antisense Technology

This is a very interesting and emerging area of genetic engineering that has been used for the selective inactivation of single genes coding for specific enzymes. The DNA molecule has two strands of which one is antisense or non-functional. In antisense technology RNA (Ribonucleic acid) is transcribed (synthesized) from the non-coding or antisense strand of DNA for a given gene. Antisense RNA forms a duplex with the normal messenger RNA (RNA which carries the message of protein synthesis from DNA) and renders the normal RNA non-functional and this inhibits the production of normal protein by messenger RNA. By applying this technology ripening of fruits cold be delayed and thus the shelf life of fruits could be increased. One product of such technology, i.e. delay in ripening of tomato, is now under review by FDA in the US. The technology will have extensive applications as it can be used for selective inactivation of specific genes involved in the production of natural toxic materials in food crops. These toxicants include caffeine, glycosides and various other materials present in many common foods.

Cancer Imaging Agents

Radioactive isotopes linked to monoclonal antibodies specific for cancer cells can be used as agents that form images of cancers. The monoclonal antibody portion of the immunoimaging agent attaches to the cancer cells when injected into the body. Gamma camera can capture the image formed by the gamma radiation's given off by the radioactive atoms. Monoclonal antibody imaging agents is hoped to be able to detect malignancies, which is not possible by the currently available procedures. Imaging agents will be able to confirm the cancer types and provide informations for selecting the best therapy. It is estimated that in the US alone there are 965,000 cases of different types of cancer per year and the monoclonal antibodies to detect these cancers will have an annual market of 400 million dollars. Companies like Centrocor, Cytogen, ImmunoMedics, NeoRX and Zoma in the US are currently working on imaging of different types of cancers.

Recombinant Dairy Products

Recombinant DNA techniques have a high potentiality of improving starter cultures and enzymes used for converting milk into cheese and other dairy products. Chymosin, a recombinant rennin obtained from microbial sources, already is used in commercial cheese manufacture. Other dairy enzymes like cheese flavouring enzyme and lactase is hoped to be produced more economically through genetic engineering. Another important area is the anticholesterol enzyme for lowering down the level of cholesterol in dairy products. Recombinant processes could produce commercial quantities of this enzyme for breaking down cholesterol in milk or milk products made for it. Companies like Dairy Food Laboratories (Waukesha, WI), Genencor (South Sanfrancisco, CA), Gist-Brocades (Chartotte, NC), Chr. Hansens' Laboraotry (Milwaukee, Wi), Lactaid (Pleasantville, NJ), Miles (Elkart, IN), Novo (Danbury, CT) and Pfizer (New York, NY) are actively engaged in this area.

Autoimmune Therapeutics

Infectious diseases as well as cancer cells are fought out in the human body by its defence mechanism called the immune system. But, sometimes the system fails to identify the intruders and may attack the normal healthy cells resulting in autoimmune diseases like rheumatoid arthritis, multiple sclerosis. These diseases are almost incurable at present. Recombinant DNA technology promises for the development of new proteins that will bring harmful and erratic activities of the immune system under control. Research work is in progress on thymosin-thymus gland hormones that modulate the immune system, Gamma interferon for the treatment or rheumatoid arthritis, Interleukin-1 and its analogs, Immunomodulators for treating rheumatoid arthritis, Cloned genes for Interleukin-1 (IL-1) receptor, D-glutamic acid/D-lysine polymer conjugates as cell receptor blocker for treating lupus, Protein A for removing excess antibodies from blood. Genetically engineered T-Cell antigen receptors are the target to treat autoimmune disorders.

Immunoassays for Pesticide Residue Tests

Like clinical diagnosis through antibody-based tests, Immunoassays offer possibilities for quicker, cheaper, simpler and more sensitive test for detecting synthetic organic pesticides. Synthetic herbicides, insecticides and fungicides are in great use both in advance as well as developing countries for the protection of crops. But, many pesticides are the cause of various human diseases including cancer. So, strict regulations have to be followed so that not even trace amount of harmful pesticides carry over into food or end up in drinking water. Immunoassays will complement the present techniques like Chromatography and other analytical procedures for detecting low levels of pesticides in crops, food, water and environment. Several companies in the US are actively engaged in their development.

Diabetes Therapy

Human Insulin was the first recombinant protein approved for the treatment of diabetes. So long insulin was extracted from pancreatic glands of animals in slaughterhouses. But, this was a very tiresome job. Now, recombinant DNA techniques are used to produce Insulin by microbes like *E. Coli.* A number of companies are engaged in this field. Besides, several companies are using genetic engineering techniques to develop new approaches like Pancreas cell transplants and autoimmune treatment to cure diabetes. Diabetes is a very serious global disease. It originates from impaired capabilities to convert glucose into energy due to faulty secretions of insulin by the pancreas. Complications from high level of glucose could be severe coma, blindness, kidney diseases, high blood pressure and other serious disorders. With the availability of insulin from recombinant DNA techniques the future of diabetics for prolonging their life is really bright.

New Products of Promise for Chicken Industry

Recombinant DNA techniques have a good potentiality to improve the production of chickens and eggs. This is a huge industry and in the US alone value of chicken broiler production for meat is about 6.5 billion dollars/yr and that of eggs is about 3.5 billion/yr. Recombinant products that can improve growth offer the biggest potential market. Vaccines to prevent diseases and infestation with parasites have a significant market. Production of low cholesterol eggs is also a major target. Present researches are aimed at:

1) Development of multiple viral disease vaccines.
2) Production of recombinant chicken growth hormone.
3) Production of transgenic poultry with improved disease resistance and growth characteristics.

4) Cloning of DNA fragments from coccidiosis organisms.
5) Microinjection of embryos and use of retrovirus to transfer foreign DNA into cells.

Growth/Healing Proteins

Growth hormones like for dwarfism and others, healing hormones for burns, surgical, wounds, ulcers, etc. and also elderly and obesity hormones offer a good potentiality for their use in human welfare. Growth and healing hormones sometimes difficult to differentiate as the same substance can act in both the cases. At present, recombinant human growth hormone to treat the dwarfs has already been marketed in the US. Others are in the process of development at various laboratories. Some of the envisaged products are:

Epidermal Growth Factor (EGF): Stimulates skin growth. It is promising for healing wounds and burns, and hopefully for treating gastric ulcers.
Fibroblast Growth Factor (FGF): May heal surface wounds as well as stimulate development of blood vessels. May also be used for heart attack patients.

Human Growth Hormones (HGH): May stimulate both soft tissue and bone repairs. Could also be useful in orthopaedic surgical operations.

Interleukin-1 (IL-1): Stimulates secretion of growth hormone. More promising as a stimulant to the immune system.

Platelet Derived Growth Factor (PDGF): Could speed wound healing and soft tissue repair. It is already in pre-clinical trials.

Transforming Growth Factors (TGF): Appears in several forms like the Interferon's. Could both stimulate and inhibit growth of Cells. Promising for wound healing and bone repair.

Angiogenesis Factors (AF): Stimulates development of blood vessels. It has the potential for applications in healing of bedsores and other skin ulcers.

Hazardous Waste Treatment

Recombinant organisms offer the possibility of degrading recalcitrant compounds for which effective organisms have not been developed as yet by conventional techniques. Chlorinated organics, especially the aromatic compounds are at present the most recalcitrant chemicals creating major environmental problems. Polychlorinated biphenyls (PCBs) are the most dangerous among them. Research works in this area are aimed at finding for a gene/genes coding for an enzyme/enzymes that will break down the compounds easily. Some of them have already been found, cloned and multiple copies have been placed in bacterial hosts cells. The transformed bacteria are many times more effective than the conventional ones. Both specific as well as broad-spectrum enzymes are needed for the purpose. For the decomposition of pesticides residues recombinant bacteria have already been developed.

Recombinant bacteria like antifrost agents, insecticides and other purposes have already been released in the environments. So, use of ones for waste treatments becomes more feasible. Some researchers are now looking for 'suicide' genes that can be inserted into bacteria and at some later time be activated to kill the host organisms and prevent their further spread in the environment.

Genencor in America already selling huge quantity of enzymes like cellulases and hemicellulases for treatment of biomass waste. The company uses genetically engineered organisms to produce the enzymes in large quantities.

Human Genome

The last decade has witnessed a phenomenal progress in different fields of biotechnology. One such field is the sequencing of 'gene' called 'genome' project or in other words 'bio informatics'. A human being has 23 pairs of chromosomes in each somatic cell. In 1994 an ambitious project called 'Human Genome Project' was undertaken at a huge expense by a number of laboratories of the advanced countries. The objective was to identify some about six billion nitrogenous base sequences (Adenine, Guanine, Thymine & Cytosine) distributed among 100,000 or so genes located on 23 pairs of human chromosome and to utilize the knowledge for the treatment of congenital diseases for which there is no cure at present. And, by June 2000 this upheaval task had been completed by CELERA GENOMICS and a few other laboratories of the advanced countries. Gene sequencing which started in late 1995 with complete genome of a free living organism *Mopholis Influenza* that causes meningitis in children is now being done in many laboratories around the world and there has been an exponential growth of new information in genomics. By now complete genome of close to 100 microorganisms are known. Among higher organisms also quite substantial progress have been made with important agricultural plant like rice and also with the model plant like *Arabidiopsis*. The ultimate objectives of such studies are to utilize the knowledge for the treatment of genetic diseases in human being and also improve useful products of agriculture and industry.

Golden Rice

Professor Ingo Potrykus and his team working at the Swiss Federal Institute of Technology, Zurich, Switzerland genetically have engineered a Japanese rice variety (TP 309) by inserting into it as many as seven foreign genes enabling the rice grain to synthesise b-carotene - a precursor of vitamin A and an extra amount of absorbable iron. Potrykus group inserted four genes from the yellow coloured attractive Daffodil flower plant that gave rice grain the ability to synthesize b-carotene from the precursor present in it. The three genes for the synthesis of iron-storage protein came from French bean, Basmati rice and from a fungus respectively. Vitamin A deficiency causes blindness among children and lack of sufficient iron affects women being responsible for many anaemia related illness. This is the first kind of rice that is genetically engineered for nutritional enhancement and the humanitarian pay off from this could be enormous. Vitamin A deficiency affects some 400 million people around the world, leaving them vulnerable to infections and blindness. And iron deficiency afflicts up to 3.7 billion people, particularly women, leaving them weakened by anaemia. It is expected very much that with the availability of this rice strain around the world the potential benefits will be great. But, the success so far does not mean that the new crop is ready for market. Protrykus and his colleagues used the *Japonica* strain of rice for their research work. But, the *indica* rice is the most common commercial strain. So, the scientists at IRRI have taken on the task of cross breeding the new strain with indica rice and field-testing the hybrid. It is expected that the results will be forth coming very soon.

Biofarming

Utilizing genetic engineering techniques the whole plants are now being used as factories for producing vaccines, pharmaceutical products, enzymes, drugs, antibodies and even biodegradable plastics. Plants have advantages over animal and bacterial cell cultures, since the plants, specially the annual types, can be easily grown and the product in question can be extracted after the plant maturation. In certain cases like banana the transformed fruit can just be eaten to get the desired immunization. And, in the near future one need to eat only a banana for protection from hepatitis B or potatoes to get immunity from colon bacillus (*E. coli*). Professor Charles Arutzen of the Boyce Thompson Institute of Plant Research and his group is the pioneer in this area of research. Likewise, industrial oil with a hydroxyl side chain has been produced in Canola corn oil by cloning and transformation of the corn by a gene from the California bay tree. Therefore, in the near future, it will be possible to produce oil of novel composition in existing oil producing crops by utilizing genetic engineering techniques. Extensive research works are also in progress to make plant synthesize polymers with plastic and elastic properties. Genes from bacteria that can produce Polyhydroxy alkanoates having plastic like properties are also being introduced into plants. Further research is in progress

Biotechnology, specially the industrial biotechnology, is expected to have a significant impact on the economy of the world within the coming decade, through the use of advanced tolls such as Genetic engineering. The enormous potential of biotechnology to provide diverse new products of therapeutic and industrial importance will usher a new era of development in the near future.

To date, major investment in biotechnology has been primarily in the health sector, the results of which are having a profound impact on medicine and health care by providing improved approaches to the diagnoses. Although health related research must remain a national priority, future research work needs to be built on the common foundation in basic science to bring the power of biotechnology to bloom in other field. In this context the area of manufacturing and bioprocessing will get a major thrust in the near future.

But, biotechnology particularly the industrial biotechnology involving manufacturing and bioprocessing is a very capital intensive venture for which specialized capacity building is necessary. And, for that reason developing countries, specially the LDCs, are lagging behind in this area.

The Biotechnology Research Subcommittee (BRS), USA in its report has emphasized the need to develop biotechnology research in different areas and has set up priorities as follows:

1. Agriculture

Agricultural Biotechnology has the potential to increase food production, reduce the dependency of agriculture on chemicals, and lower the cost of raw materials, all in an environmentally friendly manner. It offers efficient and cost effective means to produce a diverse array of novel, value added products and tools.

Research Priorities

- Continuations of mapping and sequencing of animal/plant/microbial genomes to elucidate gene function and regulation, and to facilitate the discovery of new genes as a prelude to gene modifications.
- Determination of biochemical and genetic control mechanisms of metabolic pathways in animals, plants, and microbes that may lead to products with novel food, pharmaceutical, and industrial uses.
- Extension of understanding of the biochemical and molecular basis of growth and development including structural biology of plants and animals.
- Elucidation of the molecular basis of interaction of plants and animals with their physical and biological environments, as a basis for improving the organisms' health and well being.

- Enhancement of food safety assurance methodologies, such as rapid tests for identifying chemical and biological contaminants in food and water

2. Environment

Bioremediation is the primary target of environmental biotechnology. This involves the use of living organisms or their products to degrade wastes into less toxic products and to concentrate and immobilize toxic elements, such as heavy metals, to minimize industrial wastes and rehabilitate areas fouled by pollutants or otherwise damaged through ecosystem mismanagement.

Research Priorities

- Development of an understanding of the structure of microbial communities and their dynamics in response to normal environmental variation and novel anthropogenic stresses.
- Determination of the biochemical mechanisms, including enzymatic pathways, involved in aerobic and particularly anaerobic degradation of pollutants.
- Expansion of understanding of microbial genetics as a basis for enhancing the capabilities microorganisms to degrade pollutants.
- To conduct microcosm/mesocosm studies of new bioremediation techniques to determine in a cost effective manner whether they are likely to work in the field, and establish dedicated sites where long-term field research on the bioremediation technologies can be conducted.
- Development of test and evaluate innovative biotechnologies, such as biosensors for monitoring bioremediation *in situ*; models for the biological process at work in bioremediation; and reliable, uniform methods for assessing the efficacy of bioremediation technologies.

Manufacturing/Bioprocessing

Bioprocessing- a type of advanced manufacturing that employs chemical, physical and biological processes employed by living organisms or their cellular components - will cater to the demands for new and improved commercial products. Bioprocessing can provide products with unique and highly desirable characteristics and offers new production opportunities for a wide range of items.

Research Priorities

- To investigate methods to enhance the efficiency and expand the utility of upstream processing technology.
- To develop capabilities to recover and purify products from dilute bioprocess streams and develops predictive models to facilitate the design of down stream separations.
- To develop methods for monitoring and control of commercial bioprocessing including reliable and robust real time sensors.
- To expand the development of novel biomaterials, such as bio-mimetics and replacement tissues, through new tissue engineering and chemical systems methods.

3. *Marine Biotechnology and Aquaculture*

Although oceanic organisms constitute a major portion of earth's biological resources, yet most of these organisms (primarily microorganisms) have yet to be identified. Recent advances in molecular biology, biosensor technology, aquaculture, and bioprocess engineering now promise fundamentally new approaches and opportunities for identifying, using, and managing biological resources from the seas.

Research Priorities

- To develop a fundamental understanding of the genetic, nutritional and environmental factors those control the production of primary and secondary metabolites in the marine organisms, as a basis for developing new and improved products.
- To identify bioactive compounds and determine their mechanisms of action and natural function to provide models for new lines for selectively active materials for application in medicine and the chemical industry.
- To develop bioremediation strategies for application in the worlds coastal oceans where multiple uses – including waste-water disposal,

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recreation, fishing and aquaculture demand prevention and remediation of pollution's and develop bio-processing strategies for improving sustainable industrial processes.

- To use the tools of modern biotechnology to improve the health, reproduction, development, growth, and overall will being of cultivated aquatic organisms; and promote the inter disciplinary development of environmentally sensitive, sustainable systems that will enable significant commercialisation of aquaculture.
- To improve understanding of microbial physiology, genetics, biochemistry and ecology in order to provide model systems for research and production system for commerce, and to contribute to understanding and conservation of seas.

The BRS (Biotechnology Research Sub-committee, USA) has identified three overreaching priorities for biotechnology research in the areas examined:

Overreaching Priorities

(1) Expansion of research to discover, characterize, modify and control the genetics and biochemical products and processes of a broad range of terrestrial and marine organisms for application in biotechnology.

(2) Application of the tools of modern biotechnology to problems in agriculture the environment, and manufacturing to facilitate the development of new and improved products, processes and test methods.

(3) Strengthening and enhancement of facilities, repositories, databases, reference standards, and human resources to ensure the future vitality of the biotechnology enterprises.

Bangladesh like some other developing countries may take appropriate lessons and guidelines from this report and develop research programmes accordingly. Biotechnology is poised to make major contributions to the economic growth of the world at large in the 21st century through the coordinated implementation of these research priorities.

Present Status of Biotechnology in Bangladesh

Plant Biotechnology

The programme on Plant Biotechnology in Bangladesh was initiated in late 1970s in the Department of Botany, Dhaka University with tissue culture of jute. Thereafter within a span of 10-12 years tissue culture research laboratories have developed in different universities and R&D organisations like: Dhaka University, Rajshahi University, Chittagong University, Jahangirnagar University, Khulna University, Bangladesh Rice Research Institute, Bangladesh Jute Research Institute, Bangladesh Agricultural Research Institute, Bangladesh Council of Scientific and Industrial Research, Bangladesh Atomic Energy Commission, Bangladesh Institute of Nuclear Agriculture, Bangladesh Forest Research Institute and Institute of Post Graduate Studies in Agriculture. At present, a few NGOs like DEBTECH and PROSHIKA are also working on plant Tissue culture. As a result of intensive work on plant tissue culture protocols on plant regeneration and micro-propagation have been developed on different crops, forest plants ornamental and fruit trees as well as vegetables. These in vitro regeneration protocols are now waiting for commercial exploitation. It is expected that with the establishment of private entrepreneurs commercial utilization and expansion of tissue culture techniques will gradually find its due place in Bangladesh.

Animal Biotechnology and Aquaculture

In Animal Biotechnology Bangladesh Live-stock Research Institute (BLRI) and Bangladesh Agricultural University (BAU) have already taken modern biotechnology programmes. These include Embryo Transfer Technology, Multiple Ovulation Embryo Transfer and Artificial Insemination programme. But, the programme of animal gene transfer through genetic engineering technique has yet to be started. However, livestock biotechnology produced 11 types of veterinary biologics for the treatment of infectious diseases in livestock and poultry, vaccines for foot and mouth disease and rinder-pest. Biotechnology in fisheries induces Pawing in Carp, Pabda, catfish, Koi and others. With this technology 50,000 kg of different fish species can now be produced annually.

Insect Biotechnology

Sericulture Research Institute, Rajshahi has been working for a long time for the improvement of sericulture production in Bangladesh. During recent past genetic engineering techniques have also been adopted for the purpose. At the Bangladesh Atomic Energy Commission low dose of gamma radiation to the silkworm has been employed for the enhanced production of silk. Significant progress has been achieved on Sterile Insect Technique (SIT) by utilizing gamma radiation. Besides, hormonal and pheromonal control of insects and also the Integrated Pest Management (IPM) programme are now being adopted for insect management. Isolation and characterization of *Bacillus thuringiensis* strains for the control of Lepidopteron insects has been initiated at the university of Dhaka.

Industrial Biotechnology

In the field of Industrial Biotechnology Bangladesh is yet to make real breakthroughs. Modern biotechnological programmes involving gene transfer technology have yet to be started in real earnestness. Whatever has been possible is through classical/old biotechnology methods. However, the results are quite encouraging and a good number of projects are in advanced stage that can be taken up for commercialisation. Some of these research programmes are:

(1) Bioconversion and bioprocessing have agricultural and agro industrial residues for feed, fuel and chemical.
(2) Genetic improvement of industrial microorganisms like: Citric acid production by *Aspergillus Niger* through gamma radiation.
(3) Mass scale production of Spirulina (reached commercial stage).
(4) Production of biofertilizer (Reached Commercial stage).
(5) Production of amylase and gluco-amylase for scarification of low cost starch.
(6) Production of microbial biomass protein and single cell protein.
(7) Production of tannery enzymes.
(8) Production of alcohol from agro-industrial residues – a few distilleries in the country are already utilizing more than 50,000 MT of molasses for the production of ethyl alcohol.

(9) Preservation of fruits, vegetables and spices by radiation and bioprocessing.
(10) Bio-enrichment of cereal food by microbial fermentation.

Bio-energy and Bio-conversion Technology

A significant achievement has been in the field of 'BIOGAS' production from animal excreta (cow-dung) and agricultural residues. The Institute of Fuel Research and Development (IFRD), BCSIR has been working since long in this field. As a result of research findings and its subsequent development in collaboration with Department of Energy (DOE) at present more than 10,000 biogas plants have been installed in rural areas. An extended programme to set up about 100,000 biogas plants throughout the country has also been taken up by the government that is now under implementation.

Environmental Biotechnology

In case of Environmental Biotechnology Bangladesh is yet to start its programme by utilizing modern biotechnological techniques. Whatever has been possible is through conventional methods. But, because of excessive population pressure and overall industrial activity environmental pollution is gradually increasing day by day which is causing a real threat to human health and ecological balance. Industrial effluents, municipal garbage and sewerage are discharged with minimum or no treatment at all into the surface water causing water pollution. The Department of Environment (DOE) of the Government of Bangladesh is doing some routine work only. Among the limited activities BAEC has installed advanced facilities to analyse harmful agrochemical residues at a very low concentration. Microbial technology could be a useful tool to minimize solid waste and effluents causing pollution. What is needed a broad-based 'Bioremediation' programme involving modern biotechnological approach including the development of microbes capable of degrading Xenobiotics and recalcitrant pollutants.

Genetic Engineering

Bangladesh is yet to start in real earnestness the techniques of genetic engineering for the improvement of plants, animals, and industrial microorganisms and also to combat with environmental pollution problems, etc. Only a limited number of laboratories are now working at present to introduce and utilize the gene transfer technology for the improvement of crops like rice, jute and also for obtaining better strains of industrial microbes. Research and development of animal genetic engineering is particularly very limited at present. Below is given a list of some research works that are being carried out in different universities and research institutes:

(1) Agro-bacterium mediated genetic transformation of jute being carried out at the Institute of Food and Radiation Biology, AERE, BAEC, Dhaka and Bangladesh Jute Research Institute.
(2) Genetic transformation of pulses for fungus resistance initiated at the Dept. of Botany, D.U.
(3) Genetic transformation of rice and jute for salinity tolerance and fungus resistance being carried out at the Dept. of Biochemistry, D.U.
(4) Use of DNA probes for the diagnosis of diseases being initiated at the Institute of Nuclear Medicine, BAEC, Dhaka.
(5) Development of Food, Fibre and Energy through Recombinant DNA technology being carried out at the Dept. of Zoology, R.U.
(6) DNA finger printing of rice and jute at the Dept. of Biochemistry, D.U.

National Institute of Biotechnology

The concept of a National Institute of Biotechnology in Bangladesh was developed as early as 1984 and a Project Proposal (PP) was submitted to the government by the same year. In 1993 a feasibility study was conducted under World Bank finance at a cost of 3.2 million taka with a strong recommendation for the establishment of a 'National Institute of Biotechnology'. Thereafter, the matter was subjected to different examinations and evaluation by the government for several years. Subsequently in 1998 in a meeting of the National Council for Science and Technology (NCST) it was decided that an Institute of Biotechnology would be established in Bangladesh. Accordingly, a Project Proposal was submitted to the planning Commission. Based on this report a Project Concept Paper (PCP) was prepared by the Planning Commission in 1995 and submitted to the Pre-ECNEC meeting. This after many proposals, counter proposals and revisions was finally approved by the government in a meeting of ECNEC held on 12.5.99 and accordingly a PP (Project Proposal) was prepared with an estimated cost of 20.21and then revised to a cost of 2768.24 lakh taka. The salient features of the institute are as follows:

1. Name of the Project: National Institute of Biotechnology.
2. Sponsor Organization/Ministry: Ministry of Science and Technology, Government of Bangladesh.
3. Estimated cost: 2768.24 lakh Taka (Revised)
4. Total aArea of Institute Building: 3700 sq. m.
5. Total floor space of the laboratories: 2250 sq. m.
6. No. of Laboratory: 6
7. Total No. of Scientists to work: 100
8. Expected year of completion: June 2004.

The proposed six Laboratories/Divisions of the institute are:

1. DNA Laboratory
2. Plant Biotechnology
3. Animal Biotechnology
4. Fish Biotechnology
5. Fermentation and Bioprocessing
6. Bio-energy and Fertilization

The physical construction of the institute has already been started and the main laboratory building is expected to be completed by June 2005. Appointment of Scientists for the Project period is also underway.

NIB Objectives

The National Institute of Biotechnology, Bangladesh is going to be established with an aim to accelerate the research activities in the field of biotechnology in order to meet the ever-increasing demands in food, medicine, energy and industrial sector in the country. Overall, the institute may cater to the following areas in order to boost up the application of biotechnology in the country:

(1) Research work on priority problems in agriculture, food, industry, veterinary and human health.

(2) Networking of important national projects like genome project, field testing, etc.

(3) Human Resource Development – manpower training in biotechnology, capacity building, bio-informatics and holding of regular seminars and symposia in order to disseminate the up-to date knowledge on the subject.

(4) Policy Planning – act as a national focal point on biosafety, bioethics and bio-surveillance, and also technology alert and assessment system.

(5) Technology Resource Centre – act as national centre for making use of proven, economically viable biotechnology on the shelf for fostering remunerative employment and also act as a seat of Biotechnology Park

R&D Priorities for Biotechnology and Genetic Engineering in Bangladesh

In fixing the priorities in R&D activities in biotechnology the sectors that are considered important for our country are health, energy, agriculture, industry and environment. Biotechnology can play a great role in development activities in all these sectors if R&D programmes are taken up judiciously and such programmes are supported adequately.

i) Health Sector

Development of vaccines against viral, bacterial and protozoal diseases through modern genetic techniques. Vaccines for fertility regulation, production of drugs and pharmaceuticals, etc. call for proper investment in R&D activities in biotechnology and genetic engineering.

ii) Industry Sector

R&D activities should give priority to improvement of industrial strains of micro-organisms for production of those food supplements, drugs, vitamin, hormones, solvents and other chemicals which are now solely imported from abroad. Bioconversion of agricultural wastes into food, feed and fuels is another important area. Optimisation of process parameters for maximising productivity so as to efficiently convert raw materials to finished products call for inter-disciplinary approach to the biological process with heavy input from chemical engineering.

iii) Agriculture Sector

Priorities in R&D work should include programmes on development of high yielding, stress tolerant varieties of food crops through modern genetic engineering techniques, biological nitrogen fixation, bio-fertilizers, bio-insecticides, etc.

iv) Energy Sector

Emphasis should be given on the conversion of lignocellulosic wastes to bio-fuels, improvement of biogas technology from organismal and environmental (better bioreactor) point of view, development of energy plants, etc.

v) Environment Sector

Development of efficient activated sludge process for waste treatment, development of organisms for treatment of industrial pollutants, xenobiotics, etc. should get research priority.

Biosafety Aspect

With all the benefits, which accrue from the biotech revolution, it appears some of them are associated with potential risk as well as described below.

It is estimated that over the last three decades about half of the varieties of the world have been lost. One of the major risks in view there arises from the fact that novel varieties, which are commercially attractive, may replace some of the existing varieties unless proper attention is given to bio-conservation. Again, the genetic uniformity in plants and animals makes them vulnerable to pest and diseases. An epidemic caused by a mutant bacteria, pest or virus can cause havoc to a large number of plants or animals.

So far farmers in the Third World have been able to develop varieties, organise production and also were able to control the spread of disease as they were familiar with the indigenous plant or animals they were cultivating or breeding and the diseases which were likely to affect them, either by taking preventive measure or by providing the necessary treatment. With the introduction of bio-tech seed the dependence of farmers on the supplier would increase, as the supplier alone would have the total information if any, on how to control disease problem. Because of the patent rights of biotech products the farmer would not be able further develop the variety, or experiment with it. This would turn the Third World farmers and breeders into mere workers. The problems of terminator gene have created serious controversy in this regard.

It is apprehended that biotechnology may also result in the substitution of a large number of natural products, such as flavours, added to beverage, food and other products. Their production, through cloning to increase the quality and quantity of a particular flavour may affect production of indigenous aromatic and medicinal plants. It may also affect the present genetic diversity, with consequent disadvantages, as mentioned earlier.

The genetically controlled animal produced in animal farms, would be cloned for increased quantities of proteins, but it may not suit the taste of consumers. The attempt to introduce casein gene in rice, though successful, may result in rice that taste like milk?

Again experiment on human genome has raised many ethical questions that deserve serious attention.

Finally environmental release of genetically manipulated products where one does not know the possible impacts they would have on other living forms, may result in disaster particularly when a large number of them are released for testing or for specific purpose, i.e. to combat pests, etc. without assessing other possible harmful side effect.

There is a tendency on the part of multinational companies to test biotech product without adequate safeguards over a period of time to know long-term effects. If the laws of the country do not permit and cannot be violated, then the tests might be done offshore or in the Third World countries unless those countries are guarded by strong bio-safety regulations.

Scientists in their desire to gain name and fame or to earn large financial benefits by undertaking research in manipulating genes to develop new forms of life tend to violate the laws of the country and undertake tests without considering the environmental impart.

For proper handling of genetically modified plant, animal and micro-organisms it is essential to have safety guidelines and for field application safety regulation is must to protect our environment from harmful effects if any of genetically modified organisms.

Biosafety Regulation

National 'Biosafety Guidelines' have been framed to be followed by the scientists working in the area of biotechnology.

The salient features of the bio-safety guidelines are:

(1) Procedures and guidelines on the introduction movement and field release of regulated materials.
(2) Physico-chemical and biological containment procedures and facilities.
(3) Guidelines for classification of micro organisms according to their risk assessment.
(4) Good laboratory practices.
(5) Good industrial large-scale practice.
(6) List of organisms according to different risk groups.
(7) The Universal Biohazard sign.
(8) Framework for risk assessment.
(9) Biosafety Committees.

Having set up the appropriate Biosafety Guidelines for working in the area of biotechnology, Bangladesh is now thinking to enact an 'Act' passed by the national parliament on the issue of 'Biotechnology'. The act to be named as 'The Bangladesh Biosafety Act-2001'is in its final stage of preparation prior to the submission to the government to be placed before Parliament as a bill for endorsement. The salient features of this 'Act' will be:

(1) Short title of the Act.
(2) Definitions of different terms/connotations.

(3) Formation of National Committee on Biosafety of Bangladesh (NCBB).
(4) Power and Responsibilities of NCBB.
(5) Risk Management of GMOs.
(6) Contained use of GMOs.
(7) Field Release of GMOs
(8) Public Deliberations Awareness.
(9) Restriction on certain activities related to GMOs.
(10) Working Principles for NCBB.

It is expected that after the 'Act' has been passed by Parliament, biotechnological research in Bangladesh will be done under more congenial atmosphere and bioethical problems will be taken care more diligently.

Bioethics

In response to 'Bioethics' Bangladesh recently is going to support the International Convention against human cloning for reproduction to be placed on the agenda of 56th UN General Assembly. Bangladesh strongly feels that human reproduction cloning is against the human dignity and in the long run it may also bring havoc to mankind. Universal declaration on the human genome and Human Right adopted in 1997 by the UNESCO specifies, "Practices which are contrary to human dignity, such as reproductive cloning of human beings shall not be permitted". In pursuance of this declaration any attempt to clone human being should be prevented through appropriate action/convention of United Nations, as it is contrary to 'Bioethics'.

Biotechnology Opportunities and Challenges

The opportunities of biotechnology are enormous in the field of agriculture, health care, industrial upliftment, energy development, environmental development or bioremediation. But this new and emerging technology is not without challenges particularly for developing countries. Major challenges include

- Capital intensiveness
- Specialized laboratory structure
- Commercialisation issues

- Private sector shyness
- Biosafety issues
- Bioethical issues

Bangladesh is in the threshold of entering into this modern area of science. Plant tissue culture was initiated in early 1970s, but not much progress has been made so far. As mentioned earlier, some initiation has been made in the field of animal biotechnology, aquaculture, insect biotechnology, industrial biotechnology, bio-energy and also genetic engineering. But in spite of all sincere efforts of the scientists, no breakthrough could be made because of lack of facilities and logistic support, research and development fund and incentives. However, during the last couple of years the government has given priority to the development of biotechnology

National Capacity building

Biotechnology, although a very promising technology, requires heavy investment at the laboratory, pilot scale and commercial level applications. For national capacity building the following areas need emphasis:

- Infrastructure development - laboratory building, ancillary facilities, specialized laboratories, etc.
- Manpower development - specialized expertise in the field of molecular biology, genetic engineering, protein chemistry, chemical engineering, etc.
- Equipment - for modern biotechnology work costly equipment like DNA synthesizers, protein sequencers, high-speed ultracentrifuge, pilot plant equipment for plant, animal and microbial technology work, etc.
- Fine chemicals - a regular supply of costly chemicals, enzymes, radio labelled compounds, etc.

Potentials and Requirements for a Biotechnology Development

Bangladesh has great potentials for development in the field of biotechnology. The potentials lie primarily in its rich fertile agricultural and biodiversity. Plant biotechnology, animal biotechnology, fisheries biotechnology or aquaculture, in every aspect Bangladesh has a great potential for development. We have fertile alluvial soil; our masses are accustomed to different agricultural practices. What needed are a good variety of plant and/or a good stock of animal/ poultry/ fish, etc. that can be developed through modern biotechnology. For this the country needs a good team of well trained manpower for doing research in various fields of biotechnology like genetic engineering, cell culture, cell fusion, protein engineering, enzyme technology, etc. Bangladesh has good potential for development agro-biotech industry.

A 20-year Perspective Plan

Bangladesh is yet to start with biotechnology programme in real earnestness. Although scientists were concerned with its development from very beginning, because of lack of national policy planning the subject did not get due importance with the government for a long time. Though the situation has changed over the recent years, the National Institute of Biotechnology or similar other existing research laboratories and institutes will cater only to a small fraction of national need. Therefore, a 20-year perspective plan is deemed necessary to cater the future need with respect to:

- Manpower development
- Laboratory infrastructure development
- Building centre for excellence
- Identification of priority research areas like
  - Agriculture biotechnology
  - Healthcare,
  - Industrial biotechnology
  - Bio-energy
  - Bioremediation, etc.

Related Issues

Biotechnology although has revolutionised the subject of biology, it has also created new problems in the society the principal one of which is the transfer of genes from unrelated species. Although until now no havoc has been created, a danger is always there that 'it might be created'. Therefore, research work in this area has to be done under utmost care. Development of crop plants with new properties have created suspicion in the minds of many. Again patenting and commercialisation of life forms has created new problems of intellectual piracy, monopoly business and bio-slavery. The related problems, which need to be addressed in harnessing the benefits of biotechnology, are as follows:

- Biosafety and bioethics
- Technology transfer and IPR
- Biodiversity
- Public awareness

Bangladesh, as mentioned earlier, has by now framed Biosafety Guidelines. Biosafety Act is under preparation. It is hoped that relevant issues will get serious attention from all concerned so as to reap the real benefit of biotechnology without harming present or future generation.

Conclusion

Biotechnology holds good promises for improved agricultural productivity and products. It ensures better management of agricultural echo system including water management, biofertilizers, biopesticides, biodiversity and bioremediation. In short, it can play a vital role in the socio-economic development of a country. The spectacular progress which has taken place in the last few decades indicate that we can no longer ignore the application of this technology for solving problems of agriculture, health, energy, industry and environment. However, a long term plan, adequate financial support for R&D in different areas of biotechnology, setting up of demonstration plant, etc. are necessary prerequisites for application of this innovative technology for our national development.

Recommendations of the Second Conference on Biotechnology for Asian Development

RIS in collaboration with IUCN Regional Biodiversity Programme Asia and Confederation of Indian Industry (CII) organized a two day Second Conference on Biotechnology for Asian Development "Regional Cooperation for Ensuring Access and Capacity Building", with support from UNESCO, Paris and Department of Biotechnology (DBT), Government of India in New Delhi. Some of the key recommendations are being reproduced here for wider dissemination.

—Editor

Emphasis on regional cooperation to deal with biotechnology and related safety should be a priority. Timing and resources are the key in addition to capacities. Role of education and awareness is critical to ensure not only adoption of technology but also its integration to national agricultural systems. Impacts of IPR on regional cooperation are critical and need urgent attention. In this regard, a Public-Private sector partnership is a key to success. The Conference brought together innovative partnerships. Role of biotechnology in ensuring food and nutritional securities was emphasized. However, it is early to assess the impact of this technology in Asia.

Socio-economic indicators on usefulness of biotechnology are weak and need strengthening. Responding to local needs should be a priority. The focus of private sector from this perspects needs to be futher sharpened. Public sector funding is key for R&D on issues of local and national importance. Assessment on impacts of Article 27.3 (b) on national patent regime need focus and be prioritized. Impacts of issues on IPRs and technology transfer as a part of Regional Trade Agreements need study for instance the SAFTA might provide an opportunity for SAARC.

The relationships between implementation principles of Multilateral Environmental Agreements (MEAs), especially the Cartagena Protocol and WTO need critical review. Policy makers and practitioners need to work together on developing national policies. The influences of IPRs and biotechnology is felt on legal and patent regimes in India. Recent developments on legal reviews in India might provide options for other countries in the region. Bangladesh, Thailand, Pakistan, and Vietnam country papers were presented at the conference which further refelected on these points.

The discussion under Cartagena Protocol on issues of labelling, traceability should be considering local and national situation and feasibility. Currently the global discussions do not match national capacities. It came out that experiences of countries like China, Sri Lanka, Thailand, Philippines, Cuba, Mexico and others provide a good opportunity for assessing options and constraints. The need for a national policy which is responsive, transparent and relevant to local needs is critical for furthering the agenda on biotechnology and introducing the technology at commercial scale. This is particularly relevant to Asian countries. Experiences of countries and institutions on socio-economic impacts of biotechnology reveal that identification and adoption of technologies, markets, policies and approaches that are locally relevant alone would succeed for application to development planning. A starting point in this regard for Asian economies may be to urgently look into the issue of how biotechnology is being defined. As of now, there are different definitions being used which creates hurdles in the statistical measurement of biotechnology related economic activities. Cost benefit analyses of biotechnology form an important element of decision making on adoption of technology.

The conference was attended by several international agencies included World Bank, OECD, FAO, IFPRI and ICRISAT. It was emphasised that information exchange, agreement on testing and regulatory standard harmonization at regional level can reduce costs and make adoption more affordable. There is a need for some innovative Private-Public sector partnerships. With its economic policies and national commitments by private sector, Asia may further extend experimentation on this. New initiatives for Asia like Regional Clearing House Mechanism (CHM) on biosafety, Regional Cooperative Network of Biotechnology may be considered. Some of the national agencies like US State Department, IDRC, Swiss Agency for Development for Cooperation also participated.

The conference was inaugurated by Shri K.C. Pant, Deputy Chairman, Planning Commission and Chairman, RIS, while the inaugural address was delivered by Mr. M. Tawfik, Director, UNESCO. The Secretary Department of Biotechnology, Dr. M.K. Bhan delivered the valedictory address.

Biotechnology to Improve Paper Strength

The Consortium for Plant Biotechnology Research (CPBR) has given the grant to initiate work at select research centers to explore possibilities of increasing the fiber length in trees, for stronger paper and structural wood products. Such modifications of wood properties can also improve the ability to pulp the wood and decrease the need for use of expensive and environmentally hazardous chemicals.

The study would identify ways to modify growth and wood properties in trees through genetic modification of gibberellic acid metabolism — one of the main hormones controlling plant development. The researchers have already isolated a major gene in the gibberellic acid metabolic pathway and demonstrated the effectiveness of this approach to control tree size. Altering the wood's economic properties such as the fibers and tree height can increase not only the availability of the product but its market value.

According to the CPBR, world demand for pulp and paper products is expected to increase by 50 per cent in the next 15 years. Nearly all of this increased demand will be met through the use of plantation-grown trees. Improving growth and quality factors of these trees will be instrumental in meeting the demand while at the same time preserving natural forests for environmental and biological diversity.

This and other projects funded by CPBR, will generate economic development through new jobs and value-added crops. The research will also support environmental preservation by encouraging the use of renewable resources. The CPBR is a national, non-profit organization matching US research universities with companies interested in developing improved products and processes. The research project is innovative and has the potential for contributing towards the commercial, economic and environmental development.

Technology Licence may Boost Crop Research

Commonwealth Scientific and Industrial Research Organization (CSIRO) has entered into a licence agreement with Bayer CropScience over the application of its DNA-delivered RNAi (RNAi) gene silencing technology in certain major crops. The deal is the first licence of CSIRO's patented RNAi technology to a leading agri-biotechnology company. Under the agreement Bayer CropScience acquired a worldwide license to develop, market and sell selected crop plant varieties incorporating the RNAi technology. This collaboration demonstrates CSIRO's commitment to build on its position at the forefront of the RNAi field and to work with partners to commercialise its applications. Using RNAi, CSIRO Plant Industry researchers first demonstrated gene silencing in an organism in 1995. The RNAi technology is a breakthrough technology with potential for application across a number of fields including development of novel traits in plants as well as animals.

RNAi can be used to introduce disease resistance, enhance nutritional qualities and control flowering by removing unwanted gene functions. CSIRO has already applied RNAi to make healthier cottonseed oils for cooking and margarine by 'switching off' genes in cottonseed that would otherwise produce the cholesterol raising trans fatty acids usually made as a by-product of cottonseed processing.

Syngenta to Reap Sales Growth Rewards

Syngenta has announced that it would abandon development of one of its genetically modified crops because of delays in approval. Syngenta and rival Monsanto have withdrawn "Event 77", a jointly developed herbicide-tolerant GM sugar beet planned for the European market. The variety, which was the subject of the UK's field trials on GM crops, is now considered commercially out of date.

Still the company is expecting major gains on account of higher crop prices, a benign subsidy environment and a rebound in Latin America, where sales rose 70 per cent year-on-year. Syngenta reported a 15 per cent rise in sales to $2.3bn, helped by the weak US dollar. Crop protection sales were up 7 per cent in constant currency terms, boosted by a strong conclusion to the season in Latin America and a good start in Europe, Africa and the Middle East, as well as strong demand for insecticides. Seed sales were up 11 per cent. On the performance of the company, Syngenta expected earnings per share to grow 30 per cent, before restructuring and impairment charges, in 2004, significantly ahead of its previous "high-teens" target. The increased optimism was prompted by a strong rebound in all sectors of the agrochemical market after five years of downturn in the industry, as well as synergies from the merger of AstraZeneca's agrochemical operations with those of Novartis three years ago. Syngenta's decision to raise earnings came as US chemicals company DuPont reported a rise in first-quarter earnings yesterday, partly on the back of a rebound in agrochemicals demand.

ENGL Extends to New Member States in EU

A number of national enforcement laboratories from the accession countries became part, of the European Network of Genetically Modified Organisms' Laboratories (ENGL) recently. The 24 laboratories, which previously had the status of observers, have joined the network, coordinated by the European Commission's Joint Research Centre (JRC), aimed at managing the detection, identification and quantification of genetically modified organisms (GMOs) in food and feed in Europe. Under the new EU regulations on GM food and feed, the JRC has been given the role of managing the detection methods and their validation. This means that all applications for GM food or feed must go through the JRC, which will test the product, making sure the detection methods are accurate and effective.

EU legislation requires a case-by-case assessment of all GM food or feed applications based on scientific evidence. Only products meeting these stringent requirements will be able to be sold in an enlarged EU. Providing a harmonised GMO detection system across Europe will provide consumers with greater choice and accuracy in selecting food products and boost the competitiveness of EU biotech companies. The aim of the ENGL, which with the new additions counts 71 control laboratories across Europe as its members, is to create a standardised detection system for GMOs through a platform of experts, who will be encouraged to exchange information and develop a common European strategy.

An enlarged ENGL will greatly improve the network's ability to detect and screen GMOs and provide a sound scientific basis for enforcing biotechnology legislation. Based on EU legislation, inspectors collect and screen food and feed samples for DNA or proteins that indicate genetic modification. If a screening shows the presence of one or more GMOs, regulations require that the amount be quantified. Mandatory labelling of food ingredients is guaranteeing the consumer's right to information. This pan-European network of scientific experts will improve public confidence as well as give consumers the opportunity to choose between products with or without GMOs. Moreover, the ENGL network will further help the development of the European Research Area (ERA) by expanding available scientific excellence and ensuring policy compliance in an enlarged EU.

Spain to Ban Syngenta Corn

Spain, the only European Union country where genetically modified crops are commercially grown, banned the planting of a Syngenta AG corn variety saying it may boost resistance to antibiotics. The Bt176 variety of feed corn will no longer be allowed to be sown or cultivated. Syngenta, based in Basel, Switzerland, has sold the corn in Spain since 1998. Bt176 occupies almost two-thirds of the 32,000 hectares (79,000 acres) of Spanish land given over to gene- altered crops.

Gene-modified foods and crops still arouse suspicion in Europe, where the EU hasn't approved any for commercial use since 1998. A survey published last year found that only 2 per cent of the UK population would eat gene-altered food. In contrast, such foods are now common in the US, the world's biggest biotech producer now challenging the EU's six-year moratorium at the World Trade Organization in Geneva. Eighty-one per cent of soybeans planted in the US last year were altered to make them resistant to herbicides, according to US Agriculture Department statistics, and a quarter of the corn crop was altered to make it pest-resistant. Gene-altered crops accounted for 3 per cent of Syngenta's sales of $6.6 billion last year.

Spain's food-safety agency banned Bt176 after the European Food Safety Authority published scientific advice on bio- engineered plants. The Syngenta corn contains a marker gene that the EU agency said should be restricted to field trials, because it may confer resistance to ampicillin, the Spanish agency said. The European Commission hasn't made any decision based on the advice. The European Commission won authority from EU members to end the ban last week and allow the import of a Syngenta gene- modified sweet corn, Bt11. Syngenta has applied for approval to cultivate Bt11 in the EU, Payer said.

Bayer AG last month abandoned plans to introduce its Chardon LL variety of GM animal-feed corn in the UK, saying it wouldn't make money because of conditions that UK government intended to attach to growing the crop.

Nigeria Biotechnology Development

The United States Agency for International Development (USAID) is to invest over N400 million in the development of biotechnology in Nigeria. In a memorandum of understanding between the Federal government of Nigeria, International Institute for Tropical Agriculture (IITA), and USAID signed yesterday in Abuja, the agency will be providing the said funds within the period of three years to establish a Foundation for Nigeria to take advantage of biotechnology to improve agriculture.

The Minister of Science and Technology Professor Turner Isoun who sighned the MOU on behalf of the federal government of Nigeria explained that biotechnology in the near future will be the principal technology that will be the scale against which the nations development will be measured Professor. Isoun who also spoke during the opening ceremony of the International Workshop titled Facilitating the Biotechnology potentials in West Africa organized by the National Biotechnology Development Agency, International Institute of Tropical Agriculture, and Tuskegee University with the sponsorship of the United States Agency for International Development which preceeded the MOU signing, explained that any nation that does not take advantage of biotechnology now will pay the price of a significant technological set back in the near future.

Labelling to Cost 11 per cent More

The Bureau of Food and Drugs in the Philippines commissioned a study to explore the possibility of labelling GM crops as part of the consumers' right to know and also to study the costs implications of GM food labelling in the country. The study evaluated the impact of GM food labelling in the Philippines from the standpoint of all stakeholders concerned. Focusing on two GM products, soybean and corn, significant portion of the study examined the cost implications of mandatory GM food labelling in the country and its effect to the farmers, traders and manufacturers, the government, and consumers.

Attendant costs of mandatory labelling of GM food products in the Philippines will be borne in raw material segregation and differentiation at the farm level and in manufacturing. The imposition of mandatory labelling laws will imply an additional manufacturing cost by 11 per cent to 12 per cent. With the increase in raw material and manufacturing costs, even the top earning companies in the country will not be able to absorb the increase. What is expected, however, is that part, if not all of the additional cost will be passed on to the consumers. Regardless of the type of labelling to be adopted, whether voluntary or mandatory, the Philippine government will have to incur regulatory costs in the implementation of a GM labelling policy.

Audit Finds Low Level of GM in Maize Seed

An audit of US-based GM testing laboratory Biogenetic Services Ltd (BGS) by the Ministry of Agriculture and Forestry (MAF) identified that BGS was deficient in several audited areas, including the way it was interpreting and reporting testing results. Subsequent MAF-sponsored tests of BGS-certified seed consignments have revealed a very low level of GM in two of 15 consignments tested to date. MAF has a zero tolerance for GM material in imported seed for sowing. MAF-accredited international laboratories undertake GM testing and MAF routinely audits them to ensure they meet New Zealand's strict testing standards.

The MAF as a precaution chose to retest 15 of 52 consignments of seed material shipped to New Zealand that had been tested by the BGS laboratory since January 2003. These 15 consignments represent about 80 per cent of the volume of seeds in the 52 consignments involved. The test results supplied to MAF by AgriQuality GMO Services in Melbourne showed the presence of GM material at a very low level (less than one GM seed per 2,000 seeds) in two of the 15 consignments tested. The remaining 13 consignments returned negative results. The GM construct in one consignment has been identified as LibertyLink T25. Maize containing LibertyLink T25 is widely grown in the United States and Canada. While this GM construct has been approved by Food Standards Australia and New Zealand as safe for human consumption, MAF has been advised that that the type of maize in question is grown in New Zealand for stock feed and is not used for human foodstuffs. MAF is now endeavouring to re-test the remaining 37 seed consignments previously certified by BGS and shipped to New Zealand, which represent only 20 per cent of the total. MAF will take appropriate action if any of these consignments are found to contain GM seeds.

Crops grown from seeds contaminated with genetically modified material may be grown and exported after harvest rather than automatically being destroyed. The Ministry of Agriculture and Forestry says it will take days to track down hundreds of bags of maize seeds from a consignment imported this year and which might contain small numbers of GM seeds. The accidental release of GM-contaminated seed is New Zealand's biggest, but Acting Biosecurity Minister Marian Hobbs yesterday told Parliament it was not a threat to human health or the environment. She was unable to offer any assurance that farmers who unwittingly planted the seed and might have crops destroyed would be compensated.

The Biosecurity Act covers compensation in the event of a pest or disease outbreak, and liability issues, but it is not clear whether the act can also apply to the release of GM-contaminated material under New Zealand's "zero tolerance" policy for GM contamination. MAF has said that some of the contaminated seed has probably been planted. The seed came into New Zealand after it was passed by a United States testing company which an MAF audit later found had faulty procedures. The company, Biogenic Services, is no longer allowed to test seed for entry to New Zealand.

Research on GM Wheat, Canola and Corn

Syngenta will continue with plans to develop genetically modified wheat despite a decision by rival Monsanto to suspend its own programme after protests. Monsanto planned to introduce its genetically modified wheat in the United States and Canada, but its efforts triggered opposition by environmentalists, farmers, consumers and religious groups as well as overseas wheat buyers, so the US biotech pioneer said on Monday it had suspended its plans. Syngenta has field trials currently in Germany and Spain for genetically modified wheat, and it will likely take several years for the development of its own product.

Meanwhile Monsanto has also pulled the plug on its genetically modified (GM) canola breeding programmes in Australia following a series of state moratoriums on the practice.

Monsanto would now divert canola investment into other business opportunities in the region where there was a higher degree of certainty. Monsanto may review the situation in 2005 and could change if there was a "significant change" in the environment across the states in the future. The imposition of inconsistent and restrictive trial conditions between states and the delay in trial approvals led to this decision. The suspension follows a NSW government ban on a 3,000 hectares trial of GM canola. It allowed three smaller research trials to test different varieties of the crop against conventional canola. Western Australia and Tasmania have both banned GM crops, while Victoria extended its moratorium recently on the technology by four years. South Australia also has a moratorium in place.

Syngenta has drawn plans to work on GM corn. It has moved for acquiring the rights to a glyphosate-tolerance technology for treating corn from Bayer CropScience. The technology known as GA21 is being used by Monsanto in some of its Roundup Ready corn seed products. It makes the plants resistant to applications of weedkiller so farmers can more effectively control weeds in their fields. In 2003, there were 12 million acres of RR corn planted in the United States, according to Monsanto. Syngenta said it planned to break Monsanto's monopoly on the market and would start selling GA21 in its branded corn hybrids and through seed company customers in 2005.

Currently Monsanto holds 100 per cent of the glyphosate-tolerant corn market, with products containing the GA21 event holding approximately 30-35 per cent of the market. With GA21, Syngenta will offer customers, including seed companies, a strong alternative choice in the herbicide-tolerant corn market. Syngenta said a recent North Carolina federal district court decision affirmed Bayer's ownership rights to the technology, and Bayer had been licensing Monsanto and Monsanto licensees to produce and sell GA21 for only a limited period of time. But Monsanto said that it holds a patent on the "fundamental technique" used in producing glyphosate-tolerant plants. Glyphosate is a key ingredient used in herbicides and was Monsanto's bread and butter for years through the company's Roundup herbicide until its patent on glyphosate expired in 1999. The bottom line is Bayer did not have a license for the intellectual property owned by Monsanto, and Syngenta does not have a license either, said Monsanto. Monsanto has been phasing out what it called the GA21(R) technology in favour of a glyphosate-tolerant event called "NK603." Syngenta's acquisition of the Bayer technology was one in a series of deals announced by Syngenta. The company is also buying part of Advanta BV's North American corn and soybean business seed company from AstraZeneca and Dutch sugar and foods group Royal Cosun.

UNICEF Recommends GM Maize for Zambia

Genetically modified (GM) maize can be a solution to Zambia's hunger situation if farmers pledge not to plant it, said the United Nations Children's Fund (UNICEF) goodwill ambassador in Lusaka on Sunday. The Zambian government has maintained its earlier position not to accept GM maize offered to Zambia as relief food, saying that the country still lacks biotechnology required managing the effects of products. Zambia has refused emergency food aid from the United States despite being one of the six countries affected by famine in southern Africa.

Zambian officials say the supplies of maize from the United States come from GM crops, adding that they are concerned that GM food aid could be used to grow new crops and so enter the local food chain. This could jeopardize exports to Europe, where GM food is less common than in the United States, they say. Around 3 million Zambians are facing famine after failed harvests. Some Zambians disagree with the government's position. Hungry villagers recently raided a chief's palace and stole GM food, which the authorities were refusing to distribute.

Biotechnology Increases Yields

Researchers from the Marche Polytechnic University, and the University of Verona, in Italy, recently reported that the DefH9-iaaM gene is expressed and biologically active in the Rosaceae species of strawberry and raspberry plants. Angelo Spena, Bruno Mezzetti, Lucia Landi, and Tiziana Pandolfini observed that the DefH9-iaaM gene could be used to improve fruit productivity by increasing the number of inflorescences per plant, and the number of flowers per inflorescence. This, in turn, would result in an increase in the number of fruits per plant.

DefH9-iaaM strawberry and raspberry plants, which were genetically modified and grown under standard cultivation conditions, exhibited a significant increase in the number of fruits produced, the weight and size of the fruit, and the total fruit yield. This was observed in all of the three Rosaceae species tested, namely: Fragaria vesca, Fragaria x ananassa, and Rubus idaeus. Fruit yield increase was approximately 180 per cent in cultivated strawberry, 140 per cent in wild strawberry, and 100 per cent in raspberry.

Prioritise AgBiotech Research: FAO Report

Biotechnology holds great promise for agriculture in developing countries, but so far only farmers in a few developing countries are reaping these benefits, FAO said in its annual report 'The State of Food and Agriculture 2003-04'. Basic food crops of the poor such as cassava, potato, rice and wheat receive little attention by scientists, FAO said. It also says that neither the private nor the public sector has invested significantly in new genetic technologies for the so-called 'orphan crops' such as cowpea, millet, sorghum and that are critical for the food supply and livelihoods of the world's poorest people.

Other barriers that prevent the poor from accessing and fully benefiting from modern biotechnology include inadequate regulatory procedures, complex intellectual property issues, poorly functioning markets and seed delivery systems, and weak domestic plant breeding capacity. Biotechnology, one of the tools of the gene revolution, is much more than genetically modified organisms (GMOs). While the potential benefits and risks of GMOs need to be carefully assessed case by case, the controversy surrounding transgenics should not distract from the potential offered by other applications of biotechnology such as genomics, marker-assisted breeding and animal vaccines. Agriculture will have to sustain an additional 2 billion people over the next 30 years from an increasingly fragile natural resource base. The challenge is to develop technologies that combine several objectives - increase yields and reduce costs, protect the environment, address consumer concerns for food safety and quality, enhance rural livelihoods and food security, FAO said. Agricultural research can lift people out of poverty, by boosting agricultural incomes and reducing food prices.

More than 70 per cent of the world's poor still live in rural areas and depend on agriculture for their survival. Agricultural research - including biotechnology - holds an important key to meeting their needs. Biotechnology should complement - not replace - conventional agricultural technologies, FAO said. Biotechnology can speed up conventional breeding programmes and may offer solutions where conventional methods fail. It can provide farmers with disease-free planting materials and develop crops that resist pests and diseases, reducing use of chemicals that harm the environment and human health. It can provide diagnostic tools and vaccines that help control devastating animal diseases. It can improve the nutritional quality of staple foods such as rice and cassava and create new products for health and industrial uses.

Research and commercialization data on transgenic crops show that many crops and traits of interest to the poor are being neglected. There are no major public- or private-sector programmes to tackle the critical problems of the poor or targeting crops and animals that they rely on," the report said. A large part of the private-sector investment is concentrated on just four crops: cotton, maize, canola and soybean. Six countries (Argentina, Brazil, Canada, China, South Africa and the US), four crops (maize, soybean, canola/rapeseed and cotton) and two traits (insect resistance and herbicide tolerance) accounted for 99 per cent of the global area planted in transgenic crops in 2003, the report said. One of the key constraints many developing countries are facing in adopting and adapting biotechnology innovations is their lack of agricultural research capacity particularly in plant and animal breeding, FAO said.

The private-sector research dominates global biotechnology. The world's top ten transnational bioscience corporations spend nearly $3 billion per year on agricultural biotechnology research and development. Private biotech research in most developing countries is negligible. Brazil, China and India, which have the largest public agricultural research programmes in developing countries, spend less than half a billion dollars each annually. The largest international public supplier of agricultural technologies, the CGIAR, has a total annual budget of only about $300 million for crop improvement. In the few developing countries where transgenic crops have been introduced, small farmers have gained economically and the use of toxic agro-chemicals has been reduced, FAO said. Transgenic crops have delivered large economic benefits to farmers in some areas of the world over the past seven years," the report said. In several cases, per hectare gains have been large when compared with almost any other technological innovation introduced over the past few decades.

In China, for example, more than four million small farmers are growing insect-resistant cotton on about 30 per cent of the country's total cotton area. Yields for insect-resistant cotton were about 20 per cent higher than for conventional varieties and pesticide costs were around 70 per cent lower. Pesticide use was reduced by an estimated 78 000 tonnes in 2001, an amount equal to about one-quarter of the total quantity of chemical pesticides used in China. As a result, cotton farmers experienced fewer pesticide poisonings than those growing conventional varieties. Even though transgenic crops have been delivered through the private sector in most cases, the benefits have been widely distributed among industry, farmers and consumers. This suggests that the monopoly position engendered by intellectual property protection does not automatically lead to excessive industry profits," the report said. The scientific evidence concerning the environmental and health impacts of genetic engineering is still emerging. Scientists generally agree that the transgenic crops currently being grown and the foods derived from them are safe to eat, although little is known about their long-term effects.

There is less scientific agreement on the environmental impacts of transgenic crops. The legitimate concerns for the safety of each transgenic product must be addressed prior to its release. Careful monitoring of the post-release effects of these products is essential. FAO recommends a case-by-case evaluation that considers the potential benefits and risks of individual transgenic crops. The report says that, while some benefits have been observed, adverse environmental effects have not been detected in commercial production. Continued monitoring is needed, FAO stressed. The report also stresses the need for science-based biosafety assessments. Where crops have not been cleared through biosafety risk assessments, a greater risk of harmful environmental consequences exists. Unauthorized varieties may not provide farmers with the expected level of pest control, leading to continued need for chemical pesticides and a greater risk of the development of pest resistance.

Furthermore, neither private companies nor public research institutes can be expected to develop transgenic crops for poor producers in countries that lack reliable, transparent regulatory procedures. The FAO/WHO Codex Alimentarius Commission has agreed on principles and guidelines for assessing health risks related to foods derived from modern biotechnology. Members of the International Plant Protection Convention are developing guidelines for pest-risk analysis for living modified organisms. These agreements can help harmonize regulatory procedures globally.

Four GM Products Removed from Market

Four products tested positive for traces of Genetically Modified Organisms (GMO) despite labels claiming they were 'GM free'in Cyprus. The State Laboratory made the discovery over the past year during a National Control Programme for the Detection of GMO in Food. The four products – two types of pasta and two soya minces – were subsequently removed from the supermarkets, she said. The State Lab tests food products that go straight to the consumer or raw materials that end up in the food industry. The detection programme first began in July 2003, during which 45 products labelled as 'GM Free' or containing soya and maize were tested. It ends over the next few days and a second annual screening programme will begin shortly. It is expected to test around 50 products over the next 12 months. Foods labelled as GM free must contain no traces of GMOs. Foods containing over 0.9 per cent of GM soya or maize must specify so on their label. If we find traces less than that percentage, we ask for clarification and the company must prove that contamination took place without its knowledge. In this instance, GM soya was found in products labelled 'GM Free'. The GMOs we found are not a matter of public health, but a matter of labelling. (In other words) you won't die if you have consumed these products," she said. According to Eleftheriades the foods were being tested for round-up ready soya and maize BT 176 because they were the most common modifications. They had also been through extensive testing and their use was EU approved. Although the EU's position is that these products are not a public health concern, due to the public reaction to GM foods, the EU has said the consumer has the right to choose whether or not to consume them and has a right to know what foods contain GM products.

Label such as 'GM Free' was a marketing tool to encourage consumers to buy a specific product. Therefore these products are to be tested first because the consumers are to protected. This includes trusting what is written on a label. The Health Ministry was not concerned about the four products, which tested positive on the market. However, other agencies have started checking products and soon everyone will comply. In this instance the companies themselves didn't know they were selling imported products containing GM soya. Up until recently no one was been checked and we have only just started making efforts to apply EU legislation on GMOs that came into force on May 1.

Source: Checkbiotech.org, April 28, 2004; Checkbiotech.org, April 30, 2004, Checkbiotech.org, May 10, 2004; Checkbiotech.org, May 12, 2004; Checkbiotech.org, May 13, 2004; Checkbiotech.org, May 14, 2004; Checkbiotech.org, May 18, 2004; AllAfrica.com, May 4, 2004 and MAF Press Release, May 11, 2004.

Document

Kuala Lumpur Declaration on Biological Diversity*

We, the Ministers responsible for the implementation of the Convention on Biological Diversity and of the Cartagena Protocol on Biosafety having met in Kuala Lumpur on the occasion of the Seventh Meeting of the Conference of Parties to the Convention on Biological Diversity and of the First Meeting of the Parties to the Protocol;

Alarmed that biological diversity is being lost at an unprecedented rate as a result of human activities;

Recognizing the objectives of the Convention pose enormous challenges to conventional approaches and that new solutions that recognize the interlinked nature of the issues and the three objectives of the Convention are needed to overcome many of these challenges;

Reconfirm our commitment to more effectively and coherently implement the three objectives of the Convention and achieve by 2010 a significant reduction of the current rate of biodiversity loss;

Welcoming the entry into force of the Cartagena Protocol on Biosafety;
Urge Governments, which have not done so, to ratify and implement the Convention on Biological Diversity and the Cartagena Protocol on Biosafety;
Reaffirming the significant role of indigenous and local communities in the conservation and sustainable use of biological resources;

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* The Kuala Lumpur Ministerial Declaration was adopted by acclamation at the conclusion of the high-level Ministerial Segment (18-19 February, 2004) of the Seventh Conference of Parties of the Convention on Biological Diversity.

Commit ourselves in a decisive manner to the development of an effective international regime on Access and Benefit Sharing and support relevant capacity building efforts;

Commit our Governments to integrate biodiversity conservation and sustainable use of its components into socio-economic development;

Commit our Governments to the establishment of networks of protected areas both marine and terrestrial and to the development of indicators and incentives to meet the 2010 target to reduce biodiversity loss;

Urge our Governments to take an effective role in the review of the Millennium Ecosystem Assessment during 2004 and establish a mechanism for continuing scientific assessment input into the Convention on Biological Diversity;

Create and strengthen partnerships at all levels with public and private partners to promote protected areas, equitable sharing of benefits, capacity building, the transfer of environmentally sound technology and the provision of adequate new and additional financial resources;

Urge our Governments to support the development of national and regional centres of excellence to assist developing countries and countries with economies in transition to exchange experiences;

Urge our Governments to identify and remove barriers to the exchange of key technologies for the implementation of the Convention.

Document

Note on Liability and Redress*

The questions of liability for, and redress of, transboundary damage to biodiversity and damage to biodiversity of areas beyond national jurisdiction are highly important for many different reasons, including the following:

When activities under one countries' jurisdiction significantly affect lands, ecosystems, species and other components of biodiversity across national boundaries or outside of any country's jurisdiction, it is often difficult or impossible to obtain cessation, restitution and compensation or redress (that is, to obtain funds or other resources necessary to respond to the damage);

When the person or entity that causes such damage is not held responsible or required to bear the costs of his harm, several principles of international liability and international responsibility are compromised including especially the "polluter (or user) pays principle." In essence, if he may take such actions without bearing their true costs, the responsible party receives an unearned benefit, and many others in society bear an unjustified burden;

In addition, with regard to domestic application of liability for damage to biodiversity, more experience is needed on the use of liability as a tool for enhancing positive compliance. Voluntary guidelines or principles or other tools of capacity-building may be of inestimable value in addressing these issues.

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* This background note was circulated by IUCN at Seventh meeting of the Conference of the Parties to the Convention on Biological Diversity (COP7) at Kuala Lumpur, Malaysia, February 9-20, 2004.

With the entry into force of the Cartagena Protocol, the CBD family of instruments and processes has double incentive to address key concerns relating to responsibility for harm to biodiversity. With regard to liability, the Protocol moves a step beyond the CBD's approach. Article 14.2 of the CBD only calls on the parties to "examine the issue of liability and redress, including restoration and compensation." By contrast, Article 27 of the Protocol requires the COP-MOP to "adopt a process with respect to the appropriate elaboration of international rules and procedures in the field of liability and redress for damage resulting from transboundary movements of living modified organisms," and recommends that they take only four years to "complete the process." Recognising that the research and analysis for both liability analyses will be similar, it is clearly important for the COP and the COP-MOP to join forces to address these matters.

In COP-6, the parties "requested the Executive Secretary to re-convene the group of legal and technical experts ... to review information gathered by the Executive Secretary and to conduct further analysis of pertinent issues relating to liability and redress" under Article 14.2 of the Convention. Due to lack of funds, however, this meeting was not held.

Need for Progress in the Development of International Principles

IUCN wishes to underscore the importance of the questions of liability and redress for biodiversity damage and the need to make progress on this issue. Clear and generally accepted rules on liability for and redress of harm caused in one country, or outside of the jurisdiction of any country, by persons or activities under the jurisdiction of another country are an important tool. Not only do they provide for more effective determinations of responsibility and swifter compensation for the harms caused, but the possibility of liability for harms caused often also creates a strong incentive for good corporate citizenship in the regard to the environment.

IUCN recognizes the difficulties posed by this often highly controversial issue. In light of its critical importance to the objectives of the convention, however, IUCN recommends that the COP:

Give priority attention to the development of rules or principles that can govern or guide the development and application of general principles of law relevant to the individual or collective responsibility to redress cross-border damages and those affecting areas outside of the jurisdiction of any state.

Reconvene, if possible, the "group of legal and technical experts" on liability and redress (if possible in conjunction or co-ordination with the liability process under the Cartagena Protocol), with a mandate to find and develop recommendations regarding areas of common understanding, and mechanisms for addressing or discussing open or controversial issues.

If funding or other problems limit the Secretariat's abilities to convene such a group, consider other mechanisms and partnerships to promote the necessary expert analysis and input, that will enable CBD-8, whether or not in conjunction with the work done under the Cartagena Protocol, to take positive and useful action enabling the development of necessary understandings, mechanisms and discussions.

Guidelines for National Application of Principles of Liability and Redress with Regard to Harm to Natural Resources

Beyond the critical need to create a basis for international redress, however, the COP may wish to look further into the ways that it can assist in this issue. Certain types of legal systems have not in the past relied on the use of liability as a tool for enhancing positive compliance, but are developing interest in its domestic use. IUCN does not believe that liability mechanisms alone can encourage or increase compliance, but recognizes that many useful lessons and benefits for the COP and the Parties can be derived from further examination of liability and redress issues. Accordingly, IUCN suggest that the COP authorize any expert group or other process to consider the role of voluntary guidelines on principles of national domestic liability and redress mechanisms, and/or other tools of best practice and capacity-building as potentially valuable in addressing these issues.

IUCN is ready to take part of these efforts through its network of 800 environmental lawyers from 120 countries around the world (the IUCN Commission on Environmental Law). The roster of environmental liability experts within this list includes both practical and academic experts from five continents. We believe that this resource can be useful to the CBD and its parties in the process of addressing this important issue.

In this connection, we commend to the COP the IUCN Draft International Covenant on the Environment and Development (revised 2003), available from IUCN Publications (see especially Part IX, Articles 47 - 49).

Bio Web

List of some important and useful websites related to agriculture and environment biotechnology.

Information System for Biotechnology (ISB) provides information on agricultural and environmental biotechnology research, product development, regulatory issues, and biosafety.
http://www.isb.vt.edu

The National Agricultural Library (NAL) provides access to a variety of information services and publications covering many aspects of agricultural biotechnology. Specific topics include theory and techniques of genetic engineering, plant and animal genetics, monoclonal antibodies, single cell proteins, food processing, biomass applications and risk assessment and bioethics.
http://www.nal.usda.gov/bic

A division of USDA's Animal and Plant Health Inspection Service, Biotechnology and Scientific Services regulates and issues permits for the importation, interstate movement, and environmental release of certain genetically engineered plants and microorganisms under the Code of Federal Regulations vol. 7 part 340.
http://www.aphis.usda.gov/bbep/bp

The Biotechnology Strategies and Coordination Office (BSCO) was formally established in 1993 (although it has been in operation since 1988) to provide a one-window approach for information on biotechnology in Agriculture and Agri-Food Canada.
http://www.cfia-acia.agr.ca/english/food/biotech/bsco.html

An electronic public debate about biotechnology. Of particular interest is the Commercialization of Plant Biotechnology Products.
http://www.scicomm.org.uk/biosis

Institute for Biotechnology Information (IBI) has provided comprehensive information on commercial biotechnology to hundreds of organizations worldwide - corporations, universities, and government agencies. IBI makes this information available in a variety of formats, including databases, a unique array of publications, and special studies.
http://www.biotechinfo.com

The National Biotechnology Information Facility (NBIF) will provide a single-point access to a vast store of widely distributed biotechnology data. The NBIF will encourage information sharing between researchers, promote biotechnology in Historically Black Colleges and Universities/ Minority Institutions, and provide training in biotechnology. The NBIF will also be active in developing new sources and types of biotechnology databases.
http://www.nbif.org

Providing people with differing viewpoints a neutral forum where they can come together and freely exchange ideas on the critical issues facing agricultural biotechnology, the National Agricultural Biotechnology Council (NABC), founded in 1988, counts among its membership the leading agricultural research and educational institutions from throughout the United States and Canada.
http://www.cals.cornell.edu/extension/nabc

Dedicated to increasing awareness and communications between biotechnology investors, researchers, and industry. Bioportfolio specialises in applied commercial developments utilising modern biotechnological techniques impacting on the life sciences and associated industries.
http://www.bioportfolio.com

A Technical Cooperation Network on Plant Biotechnology formed to accelerate the process of adaptation, generation, transfer, and application of plant biotechnology to contribute to the solution of crop production constraints and genetic resources conservation for the countries of the Latin American and Caribbean region.
http://rlc.fao.org/redes/redbio/html/home.htm

Monitors the safety evaluation of genetic resources; provides procedures for release and marketing of genetically modified organisms under the German legislation; maintains databases of field trials in Germany and the EU, releases of GMOs, a list of products placed on the market in the EU, and regulations in other countries.
http://www.rki.de/gentec/geneng/gentec_e.htm

Bio Stats

Statistics on US Biotechnology

In US biotechnology has expanded across different sectors. The medical market includes human therapeutics and diagnostics as well as applications in veterinary medicine. The National Institute of Health's (NIH) Human Genome Project was an attempt to construct a genetic map of humans by analyzing the chemical composition of each of the 50,000 to 100,000 genes making up the human body. The International Human Genome Sequencing Consortium, led in the United States by the National Human Genome Research Institute (NHGRI) and the Department of Energy (DOE), successfully completed the Human Genome Project in April 2003, more than two years ahead of schedule.

Building on the successes of the Human Genome Project, the Dept. of Energy has initiated an ambitious programme to achieve the most far-reaching of all biological goals: a fundamental, comprehensive, and systematic understanding of life. The Genomes to Life programme will make important contributions in the quest to venture beyond characterizing such individual life components as genes and other DNA sequences toward a more comprehensive, integrated view of biology at a whole-systems level.

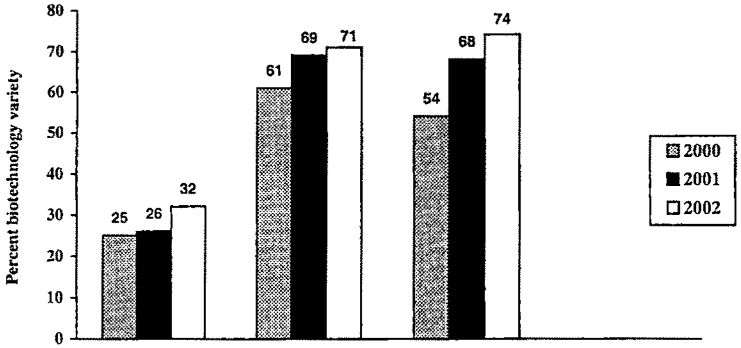
Non-medical markets encompass both agriculture and industrial applications. Agricultural applications include making plants and crops pest resistant, improving seed quality, modulating growth and ripening times, enhancing nutrient content of foods, and providing simple and inexpensive diagnostics for use in field testing for contaminants and toxic materials. Industrial uses of biotechnology involve many different sectors and include industrial enzymes, waste management, environmental cleanup, energy biomass, cosmetic formulations, and diagnostics for toxicity determinations. In the roughly 25 years since the development of recombinant DNA technologies in research laboratories, over 2,000 firms have been founded in the US to explore and take advantage of this new field.

The general public has different levels of support for biotechnology depending on the particular branch. Of the people who expressed an opinion, 90 per cent of people surveyed support genetic testing. In comparison the level of support for animal cloning is equal to the level of opposition. In all three areas of biotechnology, the proportion of people who are neutral is small indicating that biotechnology is an area where the US public has clearly formed opinions.

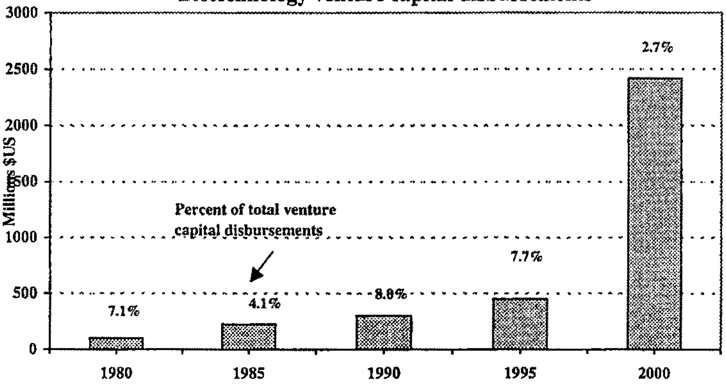
The National Science Foundation reported that the number of biotechnology research doctorates awarded has fluctuated over the period 1993 to 2001 averaging about 11 doctorate awards per year. In 2001 there were 9 doctorates awarded. In comparison, annual biometrics/biostatistics doctorates awarded averaged about 79 over the same period. According to the US Government, bio-engineered crops were planted on approximately 88 million acres in the US. In 2002 approximately 75 per cent of all soybean plantings were of a biotech variety. This has increased from just over 50 per cent in 2000. Corn in comparison is still predominantly a crop which is not planted as a biotech variety. Only a third of all corn planted in 2002 was of a biotech variety a per cent of which has increased marginally from the per cent in 2000.

Biotechnology venture capital disbursements in the US amounted to 2.7 per cent of total disbursements in 2000. This is down from a high of 11 per cent in 1992. Since 1992 biotechnology venture capital disbursement shares have been steadily decreasing over time. Unfortunately, there are no recent official figures on public biotechnology funding. However, the US Census Bureau will release data on biotechnology R&D expenditure when results of their 2002 economic census become available in May.

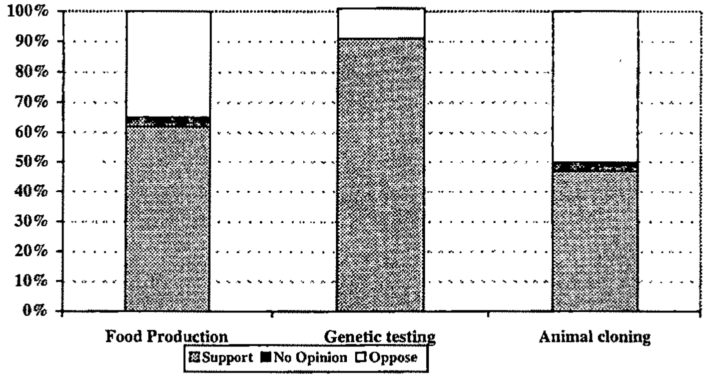
Biotechnology varieties planted, 2000-2002



Biotechnology venture capital disbursements



Public assessment of selected biotechnology applications 2001



Source: US agricultural statistics Board, NASS, USDA
website: www.usda.gov/nass downloaded March 2003
NSF, Science and Engineering 2002, appendix 7, 2002

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1. Articles should be submitted in duplicate to the Managing Editor Dr. Sachin Chaturvedi, Fellow, Research and Information System for the Non-Aligned and Other Developing Countries (RIS), India Habitat Centre, Zone IV-B, Lodhi Road, New Delhi 110003, India (Tel. 00-91-11-24682177-2180, Fax: 00-91-11-24682173/2174, E-mail: sachin@ris.org.in) Manuscripts should be accompanied by a floppy disc in IBM compatible format, preferably in MS Word, identical in every respect to the hard copy typed on A4—paper on one side only, double-spaced throughout and with ample marging on all four sides.
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4. Use figures (rather than world) for quantities and exact measurements including percentages (2 per cent, 3 km, 36 years old). In general descriptions, numbers below 10 should be spelt out in words. Use thousands, millions, billions, not lakhs and crores. Use fuller forms for numbers and dates— e.g., 1980-88, pp. 200-202 and pp. 178-84.
5. Specific dates should be cited in the form June 2, 2004. Decades may be referred to as 'the eighties'. Spell out 'the twentieth century', etc.

References: A list of references cited in the article and prepared as per the style specified below should be appended at the end of the article. Reference must be typed in double space, and should be arranged in alphabetical order by the surname of the first author. In case more than one work by the same author(s) is cited, then arrange them chronologically by year of publication.

All references should be embedded in the text in the anthropological style – for example '(Hirschman 1961)' or '(Lakshman 1989:125)' (Note: Page numbers in the text are necessary only if the cited portion is a direct quote)

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More than one reference of the same date for one author should be cited as 'Shand 1999a, 1999b'.

The following example illustrate the detailed style of referencing:

(a) **Books:**
Hirschman, A. O. 1961. *Strategy of Economic Development*. New Haven: Yale University Press.

(b) **Edited volumes:**
Shand, Ric (ed.). 1999. *Economic Liberalization in South Asia,* Delhi: Macmillan.

(c) **Articles from edited volumes:**
Lakshman, W. D. 1989. "Lineages of Dependent Development: From State Control to the Open Economy in Sri Lanka," in Ponna Wignaraja and Akmal Hussain (eds): *The Challenge in South Asia: Development, Democracy and Regional Cooperation*. pp. 105-63. New Delhi: Sage.

(d) **Articles from Journals:**
Rao, M.G., K. P. Kalirajan and R. T. Shand. 1999. "Convergence of Income across Indian States: A Divergent View". *Economic and Political Weekly,* 34(13): 769-78.

(e) **Unpublished Work:**

Sandee, H. 1995. "Innovations in Production". Unpublished Ph.D thesis. Amsterdam: Free University.

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